THE REGULATORY ENVIRONMENT FOR SCIENCE

A TECHNICAL MEMORANDUM

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Foreword

The vitality of American science is a principal component of our country's economic and intellectual success. Congress, among other institutions, bears responsibility for nurturing creativity and exploration in science while providing appropriate safeguards. Various direct and indirect forces, however, are continually altering the agenda for scientific endeavor, its methods and practices, and the dissemination of results. It is therefore essential that Congress, in providing direction and funding for science at the Federal level, understands these forces and how they are changing.

This technical memorandum, requested by the Task Force on Science Policy of the House Committee on Science and Technology, provides a "snapshot" of factors affecting science in the 1980s, and focuses on emerging issues that will require consideration by Congress.

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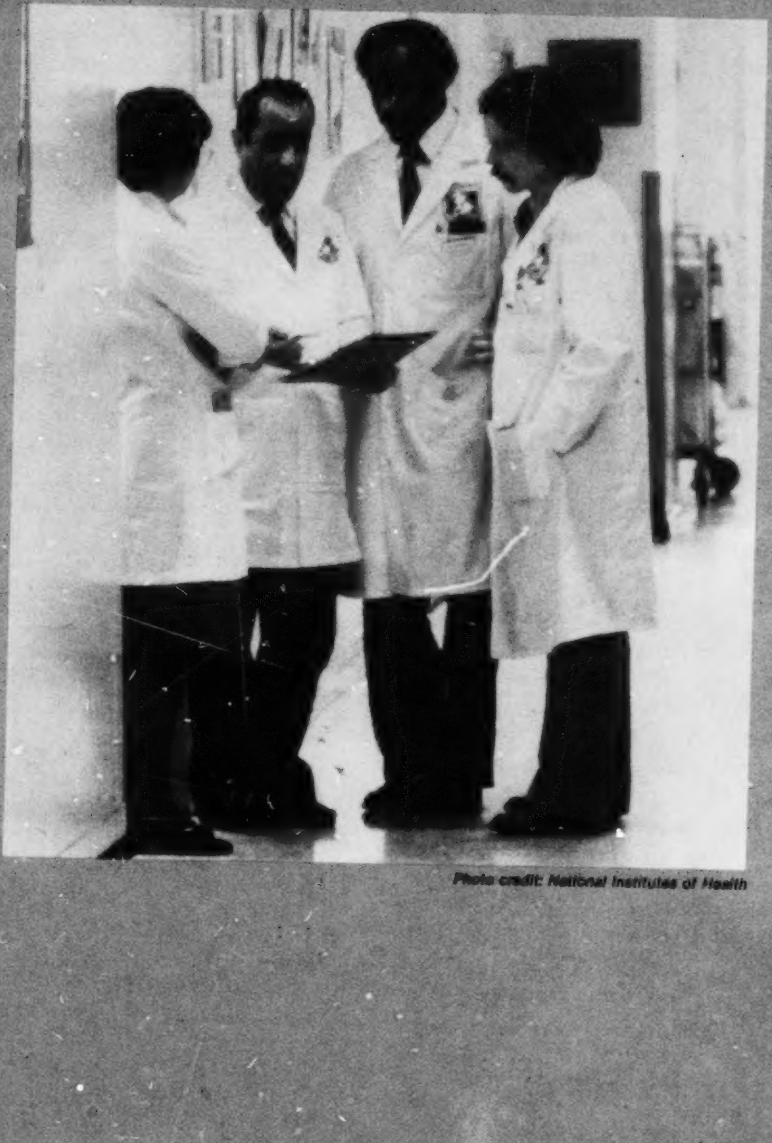
Chapter 1

Executive Summary



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Chapter 1

Executive Summary

This OTA technical memorandum examines the social and legal forces that act to restrict or regulate scientific and engineering research in the United States today. Recent controversies over the use of animals in experimentation, the risks associated with recombinant DNA research, and national security controls on scientific communication have focused congressional attention on the policy issues raised when government intervenes in the research process. As each issue has arisen, Congress has been called on to decide when and where intervention is appropriate, and how to structure intervention so as to protect public health and safety or national security without unduly retarding scientific progress. At the request of the Task Force on Science Policy of the House Committee on Science and Technology, OTA looked at the entire "regulatory environment" for research, with the goals of analyzing the structures and mechanisms for regulation and of identifying significant policy issues that may require congressional attention in the future.

Although scientists have always exercised restraints on their work, the present system of government-based, legally enforceable regulations is relatively new (ch. 2). Until 1945, constraints were limited to social prohibitions on sensitive topics, some controls on agricultural research, and national security controls on technical communication during wartime. Post-1945 arrangements for the support of science treated it as distinct from other types of government programs in that it should be free from direct government control or economic self-interest and that scientists could be trusted to govern their own affairs.

The uncovering of a number of examples of abuses of human subjects, growing fears that scientific research was posing high risks to human health, the identification of research with government-sponsored activity, and the social and political climate of the 1960s and 1970s (ch. 2), led to a series of regulatory actions that began to constrain not just what topics scientists should pursue, but also how they should be pursued and the results disseminated. More recent controversies over controls on scientific and technical information deemed vital to national military or economic interests indicate further erosion of the trust in scientists' governance which characterized the postwar arrangements. The increased regulation may also indicate that science is simply included as a target of society's increasing willingness to regulate all types of institutions, professions, or activities.

A wide spectrum of social and political rationales (ch. 3) may justify controls linked to a specific part of the research process: selection of topic, experimentation or other procedures, and dissemination of results. The moral and ethical concerns expressed in attempts to restrict research are not new. What is new, however, is the raising of such concerns to the level of government action or legally enforceable regulations. Some governmental regulations manifest concerns about the potential risks of a line of research; they demonstrate that society wants to protect the health and safety of experimental subjects. Government restraints on the communication of scientific and technical information seek to protect militarily sensitive information or to curtail economic losses associated with international technological competition. Public opinion data show that such regulation may reflect the American public's willingness to restrict research when the risk is perceived to be too great, despite the concurrent existence of widespread public support for science as a cultural activity deserving Federal support.

Analysis of the mechanisms by which restraints are imposed at the laboratory, institutional, or governmental levels (ch. 4) shows that controls in the modern research environment are widespread, synergistic, and cumulative. They affect every stage of the research process—what topics may be pursued, how they may be pursued, and when and to whom the research may be disseminated. Institutional mechanisms include formal administrative policies, institutional review committees, or institutional cooperation with external requests for constraints. Professional societies set up codes and guidelines and may cooperate with government attempts to impose dissemination controls. Government control mechanisms include: review commissions and ethics advisory boards, legislative review of proposals or projects, moratoria, regulations on the use or possession of substances used in research, interpretation of agency regulations, contract provisions, and dissemination or publication controls. The channels through which government can affect research—legal regulations, formal administrative controls, judicial actions, priority-setting through budget allocations—have increased in the last decade, largely because of increased Federal support of science (and, therefore, increased channels for implementation of regulations), but also because of general demands for accountability and the widening impact of science on society. The very multiplicity of mechanisms for restraint increases the possibility that such regulations will be implemented piecemeal, in isolation, and without coordination, and that they therefore may produce an adverse synergistic effect on the progress of science and the research base for innovation.

As the case study in chapter 5 shows, the regulatory effects, especially on the research process, are not confined to basic research in universities, even though most of the discussion of and complaints about overregulation has been concentrated there. Many of the mechanisms described in chapter 4—e.g., controls on research materials, human subjects regulation, dissemination controls—apply with equal force to research in industry and private laboratories.

In many cases, science may not have been so much singled out for control, however, as simply sharing in society's growing propensity for regulating all types of specialized institutions or activities. Such regulations include administrative reporting requirements for Federal grants and contracts, social programs legislation (e.g., affirmative action), Occupational Safety and Health Administration (OSHA) regulations and right-to-know laws, and laws and policies relating to international diplomatic relations. Although these actions are designed to serve a public objective and not to restrain research, they can add to an existing financial and administrative burden of intentional controls and their effects can be much more difficult to avoid after they are legally in force. Such regulations could have a long-term adverse effect on innovation and progress in research. There is clearly a need for better documentation and monitoring of possible unintentional adverse effects on research and, in some cases, there may be a need to consider specific legislative exemptions for research.

The local government interventions described in chapter 7, and in the case study in appendix C, point to a potential for increased confrontations between State and local authorities and the Federal Government regarding the jurisdiction for regulation. Should science be controlled through a combination of self-regulation and broad Federal oversight, insulated from local laws? The emergence of a number of cases in which research facilities have been the subject of local protests indicates that research no longer wears a mantle of unquestionable civic respectability. Instead, it is subject to the same political influences and attitudes at the local level as are other institutions.

Given these circumstances, several changes may occur in the near future (ch. 8). One is a shift in who must bear the burden of proof for control of research. That responsibility is increasingly shifting to the regulated researcher, who must prove that the research is safe or anticipate whether dissemination of the research results may have some adverse effect on the national interest. As this situation changes, the Federal Government will increasingly have to consider the appropriate role for scientists in the regulatory process itself. How much should be left to informal practice and how much required through legally enforceable regulation? Congress can also expect to confront a number of communications-related issues in the future. These issues relate to the need to protect both freedom of speech and the freedom of scientific inquiry necessary to cultivate progress and innovation. How should these freedoms be balanced with the very real need to protect national military and economic interests? Whether through ex post facto restrictions on hitherto unclassified research or through the broadening of "gray areas" of sensitive information, the short-term goals of communication controls must be balanced carefully against their long-term effects on the Nation's science and technology base and on opportunities for U.S. scientists to benefit from interactions with foreign colleagues.

Computerization of the scientific communication system may also raise in the next decade equally difficult issues regarding not only the protection of intellectual property but also the ease and speed of classification of information. Issues of patent reform will continue to create the potential for significant secondary effects on the research system—both in what type of basic research is sponsored by industry and in interference with intercollegial communication of ideas. Finally, the apparent increase in regulatory activity at the State and local level may be an indication of a jurisdictional shift in the initiative for regulation, from Federal to State or local, with the accompanying potential for "Balkanized" regulations and differential strictness of regulation.

This new "regulatory environment for research" raises many important questions for the Science Policy Task Force and for Congress. First, how can Congress assure balance among the protection of public health and safety, the rights of citizens to govern their local communities, and the freedom of individual scientists, whether of speech or action? Second, how can the regulatory process and the opportunities for public discussion of regulation be structured so that competing interests are negotiated *before* issues reach a stage of controversy and hostility? Third, which issues should receive congressional or State or local attention and which are best left to the self-regulation of the research communities? And, fourth, what can Congress do to assure that this environment does not unduly erode innovation and creativity in U.S. industry or unreasonably damage the Nation's investment in university research?

FORCES SHAPING SCIENCE

Scientific research*—i.e., the organized, systematic search for knowledge about, insight to, or understanding of a subject—is significantly influenced by its social and political context. For example, the pressures of U.S. economic competition in world markets and the linking of research accomplishments to national stature affect which research is funded and which research results may be widely disseminated. Increased public awareness of the negative side effects of the research results or processes have created pressure for government control. Thus, scientific research can be constrained both for political and social purposes, and when it is regarded as a negative force out of control or a force that may become negative if allowed to continue.

No matter what the field or institutional setting (university, government, or industry), the research process has certain common characteristics—e.g., in the use of a scientific knowledge base, in the methods of investigation, and in the training and education of its participants—that are independent of specific project goals. Restraints on research may affect the choice of which subject to investigate or which to fund (controls on topic); the method by which that investigation proceeds, including the tools of research and the objects or animals manipulated during the research (controls on procedure); and the timing of and audience for descriptions of the research and its results (controls on communication). This report analyzes the influences at each of these stages.

Different social or political mechanisms can influence the research process in different ways. Public approval or disapproval of research topics or procedures may be expressed in political demonstrations against laboratories, through referenda and local initiatives, as well as through moral condemnation and social pressure.[1]

More formal control is exercised through, for example, laws passed specifically to direct some aspect of the research process, through Federal interpretation of the language of such laws, or through the provision or denial of research funding.

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*The report is not concerned with controls on the application of research knowledge in medical practice, commercial development of a product, or similar exploitation of research results.

[1] Loren R. Graham, "Concerns About Science and Attempts to Regulate Inquiry," *Limits of Scientific Inquiry*, Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), pp. 1-22.

Other economic or political forces can affect research through government actions intended to have some other effect. Economic considerations, the need to protect proprietary interests, Federal protections on public health and safety, and other Federal and State legislation may influence industrial or other nonacademic research. For example, the Food and Drug Administration's (FDA) regulatory requirements, which govern the introduction of new drugs, are reported to have slowed pharmaceutical industry research on new drugs, particularly on "orphan drugs" (drugs for rare diseases),[2] where the cost of those regulations has not been outweighed by favorable economic and market conditions. In contrast, however, the even more stringent requirements of Nuclear Regulatory Commission and FDA regulations on radiopharmaceuticals appear not to have affected that research adversely. More favorable economic and market forces allow these firms to overcome the effect of any regulatory burden.

The attitudes and professional values of the scientific community itself have played a prominent role in influencing and sometimes constraining research activities. Self-imposed constraints were used in the 1970s, for example, during the debate over recombinant DNA. Molecular biologists exercised "restraint and caution" in their research procedures and adhered to a voluntary moratorium on recombinant DNA research, even though they "had no certain proof that the need for limitation existed or that the consequences of it would be positive."[3]

Finally, control on the communication of scientific and technical information may be implemented for reasons associated with economic or military protection. For both basic and applied research, such controls may take the form of a prior restraint on research publication or a denial of access to laboratories. When controls are imposed on basic research in universities, however, the benefits of such controls may not be perceived by the institution as outweighing the adverse effects on the education and training of students. Because such restrictions often appear to violate traditions of academic freedom, universities may oppose their implementation. Critics of sweeping controls argue that, in the long run, such restraints could harm the quality of the scientific work force, the traditional climates for creativity, and the progress in basic science which is necessary to technological advancement.

This OTA report takes a look at the entire range of social, political, and economic forces that restrain all stages of the research process, in all types of institutional settings, and that prompt changes in research projects or create sufficient political pressure for the development of legislation or administrative controls. In examining this "regulatory environment," the OTA project attempts to locate the common ground, the similarities among what on the surface may seem to involve dramatically different issues and controversies. Restrictions on communication, for example, are not only confined to basic researchers in universities. Controls and regulations—both internally and externally imposed—also affect scientists in industry and in government at all stages of research. The OTA study looks at research—regardless of where or by whom it is conducted—as a universal activity, searching for common factors in the mechanisms, justifications, and effects of the regulatory environment. A few restrictions apply equally to all parts of the research system, to industries as well as universities; others apply to specific parts of the process or only to one field. The differences may be only in the extent to which restrictions are enforced or publicly discussed.

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[2] Barry S. Roberts and David Z. Bodenheim, "The Drug Amendment of 1962: The Anatomy of Regulatory Failure," *Arizona State Law Journal*, vol. 1982, No. 3, 1982, p. 587.

[3] Clifford Grobstein, *A Double Image of the Double Helix* (San Francisco, CA: W.H. Freeman & Co., 1979), p. 2.

IMPORTANCE OF THIS ISSUE FOR CONGRESS

Increased awareness of how science and technology affect both social structure and social values and vice versa has prompted increased pressure for political intervention in what heretofore has been a decisionmaking activity dominated by scientists or science managers; but such interaction worries researchers who are accustomed to substantive control over all aspects of their own work. So there is a search underway for institutional forms that could permit more public involvement in critical policy decisions and yet still preserve "the flexibility needed for the pursuit of scientific research."[4] Congress may desire or may be asked to play a role in developing these new arrangements.

Agency regulations—and many of the secondary controls on research—are also related directly to the amount of Federal support available to scientific and engineering research and to priority setting for allocation of that support. As the Task Force document, *An Agenda for a Study of Government Science Policy,* states:

> . . . the immediate goals to which science can be expected to contribute, such as improved health, a cleaner environment, and enhanced technological innovation, cannot be considered in isolation. Broader societal goals . . . should be taken into consideration when formulating the goals for science.[5]

Another aspect that relates directly to the work of Congress is the suggestion that some regulations instituted for legitimate and laudable social or political reasons may be having secondary, unanticipated, and adverse effects on the quality of science and may thereby diminish science's usefulness to society. Regulation, according to the Task Force *Agenda,* "is one of the few areas in which the aims of science and the aims of society are not necessarily congruent. The manner in which these conflicting aims are accommodated is of significant importance to both science and society. . . ." The Task Force has focused on two aspects of this issue in particular: 1) how to shape the future regulatory environment for science while still responding to the necessity to avoid the ill effects arising from regulating science;[6] and 2) how "the legislative and regulatory authorities representing society as a whole can protect public health, safety, and values while avoiding the imposition of unnecessary restraints on science."[7]

The topic of the regulatory environment for research thus involves discussion of some of the most basic questions of American political philosophy: public control v. self-rule, Federal v. local jurisdiction, the feasibility of regulation and the importance of consent by the regulated, government regulation v. individual liberty, and how to balance the conflicting rights and values of different social institutions. The events and the debate will continue. Congress can expect to confront these issues again and again.

For many research areas, the question in the 1980s is not *whether* there should be any limits but, instead, "what those limits should be. . . . [A]nd, if we can define those boundaries, what control options will maintain them most effectively?"[8] The organized scientific community now appears to acknowledge the need for "some political and public input to the setting of the general directions and agenda of scientific research," just as the political sphere appears to have accepted the importance of "some degree of self-governance and internal agenda-setting" by the scientific community. The real issues have become, as Harvey Brooks notes, "where the lines should be drawn and the appropriate processes by which the scientific and political communities should negotiate the scientific agenda."[9]

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[4] *Panel on Science and Technology: Science and Dangers* (Washington, DC: President's Commission for a National Agenda for the Eighties, 1980), p. 19.

[5] U.S. Congress, House Committee on Science and Technology, Task Force on Science Policy, *An Agenda for a Study of Government Science Policy,* 98th Cong., 2d sess. (Washington, DC: U.S. Government Printing Office, 1985), p. 8.

[6] Ibid., p. 40.

[7] Ibid.

[8] Judith P. Swazey, "Protecting the 'Animal of Necessity': Limits to Inquiry in Clinical Investigation," *Limits of Scientific Inquiry,* Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), p. 142.

[9] Harvey Brooks, Benjamin Peirce Professor of Technology and Public Policy, Harvard University, personal communication, 1985.

Chapter 2

Historical and Political Context for Regulation of Research

Photo credit: National Institutes of Health

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Chapter 2

Historical and Political Context for Regulation of Research

e context of the current extensive and often
us support for scientific and engineering re-
in the United States, it is easy to forget that,
gh scientists have always exercised a vari-
restraints on their own work, the present
mentally imposed, legally enforceable con-
s on research topics, procedures, and com-
tion are relatively new. Most of the cur-
gulatory schemes were developed alongside
st-World War II arrangements for Federal
ng of research and were influenced by the
l attitudes and assumptions governing
rrangements and how they were instituted.

re World War II, many scientists consid-
ederal research grants to private universi-
here most basic research was conducted—
mproper if not unconstitutional.[1] In the
for example, the leaders of the National
my of Sciences "objected on principle to
private universities accept government
"[2] In part, this attitude had to do with the
ts' fears of losing autonomy. Some univer-
search was supported by the professors
lves. They were not required to account
government for their time or for minor ex-
res; "They simply did what research their
duties and their pocketbooks allowed them
"[3] But objections were also linked to con-
at government funding might provide the
unity for restraints on research, as had happened during wartime. During World War I, for example, scientists had accepted military restrictions on their communications; they were subject to censorship and were, in some cases, persuaded to delay publication until the end of the war.[4] The American Chemical Society had even opposed President Wilson's order transferring gas warfare research from Bureau of Mines control to War Department control, not out of anti-war fervor but because it "feared the numbing effect of the . . . 'red tape' of War Department methods upon the spirit of originality, daring and speed in following new trails, so essential to the successful prosecution of research."[5] The chemists predicted a "national disaster" if the "fast machine" of gas research was slowed. Such attitudes of arms-length cooperation with government were prevalent in the scientific community during the first part of the century.

Before the 1940s, industry supported a substantial proportion of the Nation's research and development (R&D) effort; the Federal Government played a relatively minor part. Scientists in the 1930s felt confident in asserting that "most of our great advances in the past have been through private initiative," including both industry and private foundations.[6] Even as late as 1940, the Federal Government paid only for about 19 percent of the Nation's $345 million expenditures for scientific research and development.[7]

Since 1940, these funding patterns have changed dramatically and, along with them, the regulatory environment for U.S. research in science and

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. Price, "Endless Frontier or Bureaucratic Morass?" *The
Scientific Inquiry*, Gerald Holton and Robert S. Morison
ew York: W.W. Norton & Co., 1979), pp. 75-92.
n 1945, Frank B. Jewett, President of the National Acad-
ciences and also of Bell Labs, opposed the creation of the
Science Foundation on these grounds. In letters to Vanne-
, Jewett stated that private initiative should furnish the
r fundamental research:

> rect or indirect subvention by Government is not only coupled
> ly with bureaucratic types of control, but likewise with politi-
> rol and with the urge to create pressure groups seeking to ad-
> pecial interests.

England, *A Patron for Pure Science* (Washington, DC:
Science Foundation, 1982), p. 35.
Penick, Jr., et al. (eds.), *Politics of American Science, 1939
esent* (Cambridge, MA: The MIT Press, 1972), p. 7.

[4] A. Hunter Dupree, *Science in the Federal Government* (Cambridge, MA: Harvard University Press, 1957); also see Harold C. Relyea, "Increased National Security Controls on Scientific Communication," *Government Information Quarterly*, vol. 1, No. 2, 1984, pp. 187-188.

[5] David Rhees, American Philosophical Society, personal communication, 1985.

[6] Robert H. Kargon (ed.), *The Maturing of American Science* (Washington, DC: American Association for the Advancement of Science, 1974).

[7] John R. Steelman, *Science and Public Policy*, vol. 1 (New York: Arno Press, reprinted from 1947), p. 11.

engineering. As the Federal Government has assumed an ever larger share of all U.S. research funding, the institutional responsibility for nourishing the research system has begun to shift. In 1960, the government was funding about 57 percent of all basic and applied research in the United States; industry, 37 percent; universities, 3 percent. By 1985, the government's share was nearly 50 percent; industry's, over 41 percent; and universities', 6 percent. The responsibility for basic research also appears to be shifting to the Federal Government (from 60 percent in 1960 to almost 67 percent in 1985) while the responsibility for applied research has shifted to industry (from 40 percent in 1960 to nearly 55 percent in 1985). (See table 2-1.) Who funds and sponsors research can have considerable impact on the locus for regulation and on the type of regulatory mechanism chosen. The shifts of funding source in the last 5 to 10 years, therefore, may be one explanation for the signs of strain described in this report, as industry becomes subjected to regulations originally intended for basic research conducted in a university setting (e.g., recombinant DNA regulation), and universities are asked to comply with regulations originally intended for industry.

Table 2-1.—Funding of Research and Development by Source in 1960 and 1985

	1960	1985
Basic research:		
Federal Government	60.0%	66.6%
Industry	28.5	18.7
Universities/colleges	6.0	10.0
Applied research:		
Federal Government	56.0	39.7
Industry	40.0	54.6
Universities/colleges	2.0	3.6
Basic and applied research:		
Federal Government	57.0	49.5
Industry	37.0	41.4
Universities/colleges	3.0	6.0
Development:		
Federal Government	68.0	45.2
Industry	31.6	54.3
Universities/colleges	—	—
Research and development:		
Federal Government	64.6	46.7
Industry	33.4	50.0
Universities/colleges	1.0	2.0

SOURCE: Division of Science Resources Studies, National Science Foundation, 1985.

Prior to the postwar infusion of Federal funds, government aid to science in the universities had also been managed with a philosophy of "loose control"—sponsors of unclassified research left the researchers more or less free to conduct their research as they believed scientifically appropriate and free to disseminate their results, subject to minor supervision and general accountability. The scientists perceived any threat to their autonomy as a questioning of their authority and expertise. During World War II, of course, that autonomy had been curtailed, but after the wartime security restrictions were lifted, government control of research tended to return to the prewar management model, expressing a basic political trust in the productiveness and reliability of scientists. George Pimentel, Professor of Chemistry at the University of California at Berkeley, characterizes that post-1945 philosophy as one of "fund creative people, but don't tell them what to do."[8] Especially over the last 40 years, however, the climate of unassailable autonomy has evolved into the current climate of strong economic support coupled with attentive direction. Researchers now operate in a mixed environment of incentives and restrictions,[9] which often replace scientists' own professional judgments about what subjects to work on and how to proceed.

A quite different shift in emphasis has also occurred in where the research is performed and therefore in who actually does the research. In 1940, 70 percent of government-funded basic research took place in government facilities. By 1944, only 30 percent was performed in government facilities; 50 percent was performed by private firms; and 20 percent in universities.[10] After the war, the pattern of funding again changed, but the distribution among performers remained similar. Industrial spending for R&D began to increase. By 1982, industry was carrying out even more of the Nation's research (72 percent); universities, 9 percent; Federally Funded Research and

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[8] U.S. Congress, House Committee on Science and Technology, Science Policy Task Force, Hearing, Feb. 28, 1985.

[9] Thane Gustafson, "Survey of the Structure and Policies of the U.S. Federal Government for the Support of Fundamental Scientific Research," *Systems for Stimulating the Development of Basic Research* Washington, DC: National Academy of Sciences, 1978), p. I-82.

[10] David Noble, *The Forces of Production* (New York: Alfred A. Knopf, Inc., 1984).

Development Centers, 3 percent; nonprofit institutions, 3 percent; and government labs, 13 percent.[11] The impact of this shift was to extend government control of research—through grant and contract provisions—into the private sector.

Finally, the discovery during World War II—and in the subsequent U.S. nuclear program—that basic research could have considerable value for maintaining the Nation's military security led to a fourth change in how science was funded and organized. Increased Department of Defense spending led to an increased proportion of research either totally classified—and hence performed away from traditional research networks—or else having the potential for classification (or similar control) because of its potential military applications. The course of the last 40 years has also seen significant shifts in the proportion of basic research sustained by the defense agencies and, as a consequence, shifts in the climate of more or less classification of new areas of basic research.

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[11] William C. Boesman, Science Policy Research Division, "U.S. Civilian and Defense Research and Development Funding," Report No. 83-183, Congressional Research Service, Aug. 29, 1983.

CHANGING POLITICAL CONCERNS*

Before World War II, national politics had only minimal influence on the research agenda for science and engineering. Because the Federal Government funded very little university research, for example, it did not have the administrative mechanisms for exerting influence. Only in a few selected fields, such as agriculture, did the agenda respond to political influence.[12] Moreover, even if scientists wanted society to benefit from their activities, the traditions of science offered no patterns to guide them and few mechanisms through which to provide advice to society. Scientists who were distrustful of government argued that financial dependence on government might damage the "autonomy of their intellectual activities" in unpredictable ways.[13]

This independence was put aside temporarily during World War II, when thousands of scientists and engineers worked, either as military or civilian personnel, in such government research projects as the Committee on Medical Research (part of the Office of Scientific Research and Development (OSRD)) and the Manhattan Project. Most were required to shift to a different line of research. They conducted their inquiries under government control and with government funding. Although new and different, this relationship with government proved to be successful for both parties.

As the war was ending, the scientists who had been administering the Federal research effort began to discuss how the science-government relationship might be sustained and structured after the war. The incentives were many. Not only had World War II fostered the creation of a formal administrative relationship between government and science but the results of scientific projects such as radar and penicillin had also demonstrated the power and potential of government-funded, government-directed science. By and large, the community of scientists and friends of science agreed on the need for a government agency to channel funding for basic research. They disagreed, however, about the institutional structure of such an organization and about who would exercise (and to what extent) political control over the research agenda.[14]

There were two well-defined perspectives on how the postwar relationship should be structured. The most prominent spokesman for a model of loose Federal control was Vannevar Bush, a Massachusetts Institute of Technology engineer who was Director of the wartime Office of Scientific Research and Development, President of the Carnegie Institution of Washington, and a principal science advisor to President Roosevelt. Actively opposed to the Bush position was Senator Harley Kilgore, (D-WV), who was supported by such scientists as Harold C. Urey, Edward U. Condon, and Harlow Shapley. A group within the executive branch, led by Presidential Assistant John R. Steelman, also opposed the Bush position and participated in the postwar debate on how the National Science Foundation would be structured.

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*This section benefits from work done at OTA by George Hoberg, Massachusetts Institute of Technology, in August 1984.

[12] André Mayer and Jean Mayer, "Agriculture: The Island Empire," *Daedalus*, vol. 103, summer 1974, pp. 83-96.

[13] Lewis E. Auerbach, "Scientists in the New Deal," *Minerva*, vol. 3, summer 1965, pp. 457-482.

[14] Noble, op. cit., p. 192.

Bush's perspective on control of research was most clearly articulated in the 1945 report *Science —The Endless Frontier.* Written at President Roosevelt's request, the "Bush report" outlined a plan for organizing science after the war. Bush wanted to create a secure funding base for American scientific research while protecting science's traditional independence in matters of agenda, procedure, and communication. Because there had been such clear separation between science and government before the war (and because the circumstances that had brought them together during the war were clearly unusual), the Bush report had to construct a basic argument for support. It found the justification in a classic American metaphor: "Basic United States policy" had traditionally been to advance all types of frontiers, thus the Federal Government must take on new funding responsibilities to assure adequate cultivation of those "areas of science in which the public interest is acute" but where private sources may not supply sufficient resources.[15] "Scientific progress is essential," the Bush report stated, to wage war on disease, to assure the future of American industry, and to prevent future military conflicts.[16]

In its plan for how such responsibilities would be fulfilled, the Bush report provides a measure for subsequent change in the regulation and control of research. The report proposed five principles to guide the government's new role in science: 1) Whatever the extent of support may be, there must be stability of funds over a period of years so that scientists may undertake long-range research programs. 2) The agency to administer such funds should be composed of citizens selected only on the basis of their interest in and capacity to promote the work of the agency. They should be persons who understand the peculiarities of scientific research and education, but need not be scientists. 3) The agency should promote research through contracts or grants to organizations outside the Federal Government, but should not operate any laboratories of its own. 4) Control of policy, personnel, and the method and scope of supported research should be left to the research institutions themselves. 5) And finally, the agency should be responsible to the President in that policies and procedures would be guided by the executive branch. The advocated policy was that "scientists should have control over how these funds were distributed, to ensure that the best science was supported as it had been by OSRD during the war."[17] Bush was not, however, "asking for free access to the Treasury; funds expended in this way would represent only a small proportion of those spent on research and development through the mission agencies of the Executive Branch . . . ."[18]

Although the report acknowledged the necessity of wartime security restrictions, it advocated that, when the war was over, scientists should once again enjoy freedom of inquiry. Controls should also be lifted on scientific information—especially that related to medicine—of potential use to civilian institutions.[19] Bush believed that removing the wartime controls would help to recover "that healthy competitive scientific spirit so necessary for expansion of the frontiers of scientific knowledge."[20] Scientific progress, the report continued, results from "the free play of free intellects, working on subjects of their own choice, in the manner dictated by their curiosity for exploration of the unknown."[21] And open publication of the research would be to the benefit of the Nation.

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[15] Vannevar Bush, *Science—The Endless Frontier,* a report to the President on a Program for Postwar Scientific Research (Washington, DC: National Science Foundation, 1980 (reprinted from Office of Scientific Research and Development, 1945)), p. 12.

[16] Ibid., p. 5.

[17] Alex Roland, testimony before the U.S. Congress, House Committee on Science and Technology, Science Policy Task Force, Mar. 7, 1985.

[18] Ibid.

[19] Bush, op. cit., p. 28.

[20] Ibid., p. 12.

[21] Ibid.

One of the committees that assisted Bush, the Committee on Science and the Public Welfare,* gave strong support to the idea that traditional models of university research be preserved. University research must not be "distorted" by the government's encouragement to examine short-range problems at the expense of more fundamental problems, for ". . . the freedom of the scientist may be decreased by the introduction of some degree of commercial control."[22] Society must guard science against too much control by industry as well as by government. That committee urged the new agency "to devise ways and means of allocating funds in large measure *without determining what particular problems are to be worked on and who is to carry them out*." "Variety" and "decentralization" foster novelty, they wrote.[23]

The Medical Advisory Committee voiced similar concerns. If Federal aid was "misdirected," it could do "serious harm" to the development of medical science. Therefore, the new agency's direction and policies should be administered by people "who are experienced in research and who understand the problems of the investigator."[24] The government should encourage "individual initiative and freedom of research." Control that is too close (or, in the Committee's words, "regimentation") could lead to "mediocre work" and "disastrous impairment . . . of research itself."[25]

Industry-based research, if it was to flourish after the war, also required some special arrangements. Patent laws designed to "stimulate new inventions" would "make it possible for new industries to be built around new jobs and new processes" and would help small industries, the Bush committees asserted. Although they were concerned about the domination of markets by big industry, the committees did not support government ownership of patents;[26] patent policy was to be left to the discretion of the new science agency's governing board.[27]

These and many other of the Bush report's recommendations were subsequently incorporated in legislation (which Bush helped to draft) introduced by Senator Warren Magnuson (D-WA) in 1945.

The Bush report did not, however, represent a consensus in either the scientific or political communities. During the war, Senator Harley Kilgore held a series of hearings on post-war planning for science, before a subcommittee of the Senate Committee on Military Affairs. And in 1945, he introduced a bill which expressed his ideas for a national science foundation. He favored a director who was appointed by and much more politically responsible to the President than had been advocated in the Bush report. Moreover, Kilgore's position was that "organizations receiving funds should be free to conduct their research and development work in a manner which they think most productive, subject only to a routine supervision and review by the foundation."[28]

Soon after the publication of *Science—The Endless Frontier,* President Truman's Scientific Research Board, objecting to what they considered to be an "underlying anti-democratic sentiment" in the Bush report, issued their own report. The White House study, directed by John R. Steelman, placed the basic questions of science policy in a political context: "Public policy cannot be shaped in a vacuum and recommendations for a national policy on science must necessarily reflect many considerations but remotely connected with the laboratory."[29]

The "Steelman report" was just as effusive as the Bush report in its praise of the social benefits emanating from scientific advance and in the tone of its underlying rationale for support of science: "It is difficult to think of any other national activity which more directly benefits all the people or which makes a larger contribution to the national welfare and security."[30] But, despite agreement on the need for a significant Federal role in funding basic science and in training scientific personnel, the reports differed on the organization of funding and on the control of the research process. The Steelman report did not object to funding research in government laboratories; it recommended maintaining the extant distribution of funds among universities, industry, and government labs[31] and it recommended that the new agency's director be appointed by and responsible to the President.

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*Chairman of the Committee was Isaiah Bowman, President of the Johns Hopkins University.

[22] Bush, op. cit., p. 91.

[23] Ibid., p. 94.

[24] Ibid., p. 62.

[25] Ibid., p. 63.

[26] Daniel Kevles, *The Physicists* (New York: Alfred A. Knopf, Inc., 1978), pp. 342-344.

[27] Merton J. England, *A Patron for Pure Science* (Washington, DC: National Science Foundation, 1982), p. 14.

[28] Penick, et al., op. cit., vol. 1, p. 6.

[29] Steelman, op. cit., vol. 1, p. 6.

[30] Ibid., vol. 1, p. 26.

The Steelman report also concluded that government security regulations should not be applied widely but instead should be applied "only when strictly necessary and then limited to specific instruments, machines or processes. They should not attempt to cover basic principles or fundamental knowledge."[32] In the conclusion to Volume I, "A Program for the Nation," the report states:[33]

> . . . it is sometimes argued that . . . the world is in its present state because the physical sciences have developed too rapidly and have unleashed forces too strong for us to control. It has even been suggested that a moratorium should be called in science, while we catch our breaths.
>
> This is a doctrine of weaklings and of men of little faith in the ultimate capacity of our people. There can never be too much knowledge, though it can be discovered at uneven rates in various fields. The cure is not to slow down the runner who is ahead—but to extend a helping hand to those who are behind.

The differences between the Bush and Steelman reports represented more than the usual political disagreements about the administration of a new agency. They reflected fundamentally different conceptions of the relationship between government and science. The political perspective represented by the Kilgore hearings and the Steelman report regarded science as a special interest. Although large-scale government support for science was a new phenomenon, science was not considered to be sufficiently different from other policy areas to warrant any special political relationships.[34] The characteristics of science were not believed to "justify a departure from our traditions of democratic government or from tested principles of administrative organization,"[35] including the principles of close accountability and avoidance of the concentration of power.

The conservative view represented by the Bush report regarded government intervention as a potential threat to scientific liberty,[36] an attitude viewed by some as reflecting a lack of faith in the competence of government administrators. But the Bush report supporters were also convinced that science was distinct from other types of government programs, that it must be free from political control, and that, to be successful, scientists should be able to direct their own affairs. Non-scientists might administer the foundation but it would be the scientists who, through advisory groups and a system of review by scientific peers, would decide how research should be conducted and would influence the research agenda. This demand to have "support without control," according to one commentator, amounted to "bestowing upon science a unique and privileged place in the public process—in sum, for science governed by scientists, and paid for by the public."[37]

On July 22, 1947, Congress passed legislation (S.526, National Science Foundation Act of 1947, 80th Congress, 1st session) to establish a National Science Foundation (NSF). This legislation contained no patent provisions, no authority for support for the social sciences, no mechanisms for geographical distribution, and a large degree of autonomy from Presidential control.[38] The governing structure was the most important point of argument, however. When President Harry Truman vetoed this first NSF legislation, he objected primarily to the bill's provisions for lack of political control. In his veto message, Truman stated:[39]

> . . . this bill contains provisions which represent such a marked departure from sound principles

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[31] Ibid., vol. 1, p. 27.

[32] Ibid., vol. 3 p. 37.

[33] Ibid., vol. 1, p. 68.

[34] Noble, op. cit., p. 15.

[35] Steelman, op. cit., vol. 1, p. 31.

[36] England, op. cit., pp. 35-36.

[37] Daniel S. Greenberg, *The Politics of Pure Science* (New York: New American Library, 1967), p. 107. There was precedent for this arrangement in the National Advisory Committee on Aeronautics (NACA), of which Bush was chairman in 1939. See James Killian, *Sputnik, Scientists and Eisenhower* (Cambridge, MA: The MIT Press, 1977).

[38] England, op. cit., pp. 78-80.

[39] *Congressional Record,* vol. 93 (Washington, DC: U.S. Government Printing Office, Nov. 17, 1947), p. 10568.

> for the administration of public affairs that I cannot give it my approval. It would, in effect, vest the determination of vital national policies, the expenditure of large public funds, and the administration of important governmental functions in a group of individuals who would be essentially private citizens. The proposed National Science Foundation would be divorced from control by the people to an extent that implies a distinct lack of faith in democratic processes.

Three years later, after extended debate and political maneuvering, another bill was passed by Congress (National Science Foundation Act, May 10, 1950, 64 Stat. 149) and signed by President Truman. This bill represented a compromise between the opposing political groups, but probably reflected the preferences of a substantial portion of the scientific community. The director of the NSF would be appointed by the President, and the bill included a mandate for evaluating and coordinating all Federal research efforts. It also provided that these responsibilities be shared with a part-time National Science Board, organized along the lines suggested by Bush. The bill did not change patent granting procedures.

The Foundation's first director, Alan Waterman, was previously the chief scientist at the Office of Naval Research (ONR). He considered any "centralized evaluation of Federal research impossible and inappropriate."[40] His experience at ONR undoubtedly influenced the shape he gave to the new foundation, for that agency had maintained an unusual contract research program, especially in basic research. Established by an Act of Congress in 1946, ONR was to "provide scientific liaison with the War Department and with that novel and highly effective civilian organization, the Office of Scientific Research and Development."[41] The philosophy that guided ONR was best understood in its view of the basic researcher as one "motivated by curiosity and interest in science rather than applicability," and the administrator as influenced by the agency's "practical mission." The key was to keep these perspectives separate: "In this way selected mission-related basic research may be supported. . . without controlling or disturbing the aim of the investigator or the course of the research."[42] The ONR contracting system extended the traditional military R&D contracting with industry to research establishments, particularly academic institutions, thereby enabling the government to utilize the most skilled scientists and engineers available to do weapons research.

After several years of debate between the Budget Bureau, NSF, and other agencies over NSF's role in Federal science policy, on March 19, 1954, President Eisenhower issued Executive Order 10521 that established the new agency's role.[43] NSF's role in policy development and evaluation was to be "cooperative rather than . . . regulatory." NSF was not made the principal Federal sponsor of basic research; instead, the order sanctioned a pluralistic system of Federal support. It encouraged other agencies to sponsor basic research that was "closely related to their missions."[44]

The Order declared that one of the purposes for NSF's establishment had been to develop and encourage pursuit of an appropriate and effective national policy for the promotion of basic research and education in the sciences. From time to time, NSF would recommend to the President Federal policies that would strengthen the national scientific effort and it would furnish guidance toward defining the responsibilities of the Federal Government in the conduct and support of scientific research. The Foundation, in concert with each Federal agency concerned, would review the scientific research programs and activities of the Federal Government in order to formulate methods for strengthening the administration of such programs and activities by the responsible agencies; it would study areas of basic research where gaps or undesirable overlapping of support may exist; and it would make recommendations to the heads of agencies concerning the support given to basic research.

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[40] Kevles, op. cit., p. 360; England, op. cit., p. 149.

[41] Alan T. Waterman, "Pioneering in Federal Support of Basic Research," *Research in the Service of National Purpose: Proceedings of the Office of Naval Research Vicennial Convocation*, F. Joachim Weyl (ed.) (Washington, DC: Office of Naval Research, 1966), p. 3.

[42] Warren Weaver, quoted in Weyl, op. cit., p. 5.

[43] England, op. cit., ch. 10.

[44] Ibid., ch. 15.

Sharp divisions over the political control of research were not unique to the debate on the National Science Foundation. In the late 1940s and 1950s, intense debate preceded the creation of both the Atomic Energy Commission (AEC) and the National Aeronautics and Space Administration (NASA), debates that also focused on patent policies, communication restrictions, and mechanisms for political control of each agency.

The legislation creating the Atomic Energy Commission—the Atomic Energy Act of 1946 [Public Law 585]—gave the Federal Government "an absolute monopoly over all aspects of atomic energy research, development, and production," including provisions to control the dissemination of data related to atomic weapons and the production, or use of fissionable material.[45] This tight Federal structure essentially removed control of even peacetime atomic energy research, or research directed at civilian power applications, from the scientific community that had developed the research field in the first place. Moreover, it created a situation in which all atomic weapons or atomic energy information was "born classified." As political analyst Harold Relyea and others have pointed out, these provisions meant that no special governmental effort was necessary to bring such information under the statute's "umbrella of secrecy."[46] The Act also prohibited the issuance of patents for inventions useful in the production or utilization of fissionable material. Although these patent provisions were relaxed somewhat in the subsequent Atomic Energy Act of 1954 and although that revision also authorized the controlled involvement of private industry in nonmilitary atomic technologies, many of the most stringent controls on research initiated by the original Act—including those on who may do such research or have access to technical information for such research—remained in force.

The initial legislation in 1958 to create the National Aeronautics and Space Administration contained language that would have created a much looser policy on patents for that agency. But draft bills in both the House and the Senate, which modeled their patent provisions on the Atomic Energy Act, would have enabled the government to maintain ownership of patents generated by NASA-funded research. The final legislation gave patent ownership to the government, but also gave the administrator of NASA the authority to waive title. Similar discussions and debates over the political control of research or of research products took place during the development of other Federal agencies and programs.

Another critical outcome of the postwar support of science was the burgeoning of the National Institutes of Health (NIH), which before the war had been a small "oldline" Federal health research organization. The Public Health Service had been created in 1912 to increase biomedical research directly related to large public health problems. At the end of the 1920s, an effort to establish NIH promoted a stronger Federal role in the encouragement of research, and in 1930, the Ransdall Act expanded and redesigned the Hygenic Laboratory of the Public Health Service into NIH. Public and congressional desire to find a cure for cancer resulted in the creation of the National Cancer Institute in 1937.

During World War II, advances in biomedical research had helped to demonstrate dramatically the effects of Federal funding of biomedical research. This success reinforced intensive lobbying during the 1950s, by public interest groups and a number of powerful individuals, for aggressive NIH-funded research focused on specific health problems. Congress often responded to this pressure by identifying and funding research areas that had broad public appeal, but that were scientifically misunderstood. The director during this period, James V. Shannon, was able to moderate, however, between the call for targeted research and the need for basic medical research; he persuaded Congress that funding of both basic and applied research was essential to reach the goals of diagnosing and curing disease.

Reflecting on the sweep of events during the formation of the current bureaucratic arrangements for science, Don K. Price has observed that the scientists engaged in constructing these arrangements adopted a three-part tactic to avoid, in particular, the constraints in choice of topic which had characterized pre-war agricultural research.[47]

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[45] Harold C. Relyea, "Information, Secrecy, and Atomic Energy," *New York University Review of Law and Social Change*, vol. 10, No. 2, 1980-1981.

[46] Ibid., p. 269.

[47] Price, op. cit., p. 77.

First, they sought to combine research with university teaching. They regarded such an arrangement as "the best way of strengthening basic research in the one setting most free of commercial self-interest or political pressure—the university,"[48] thereby obtaining a stable base from which to defend science's independence against "popular passions or economic self-interest." *Second,* they focused on the mechanism of the project grant, because it "offered a tactic to avoid detailed congressional control of funds" and also allowed Federal support to universities "without adopting a general program of aid to higher education."[49] And *third,* the pattern of organization proposed by the scientists gave them a political authority not dependent on popular votes.[50] In many cases, they gained this control through a growing system "of policy planning by part-time advisers under government grants and contracts." But as Price notes carefully, the authority gained by the scientists was not the type defensible as a Constitutional right; rather, it was a delegated authority. "[I]t depended on the continued confidence among elected politicians in the assumption on which the tacit bargain was founded—that basic research would lead automatically to fruitful developments."[51]

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[48] Ibid., p. 78.

[49] Ibid.

[50] Ibid.

[51] Ibid., p. 80.

THE 1960s: PUBLIC CRITICISM OF SCIENCE

In the 1960s, questioning of several of these basic assumptions began to shape a new political receptivity to science. More and more questions were raised about the negative effects of scientific knowledge, including both its informative value and its use as technology. News reports of calloused abuse of human subjects in scientific experimentation led to political calls for increased social accountability. Vigorous criticism of science came from a number of quarters: intellectual and theological questioning of the philosophical foundations of science; the linking of science with war (which came out of the protest against the Vietnam war and nuclear escalation); concerns about science's "technological side effects" on the environment; and ethical questions about research procedures. As a 1971 Organisation for Economic Co-Operation and Development report, *Science, Growth, and Society,* observed, "Scientific research itself became associated in the minds of many with war, and with environmental and social deterioration resulting from the large-scale application of technology."[52]

It is important to recognize, however, that theological or political efforts to control or regulate research are neither unique to the United States nor new. In 1927, for example, an English cleric suggested that "every physical and chemical laboratory be closed for about ten years to enable society at large to assimilate the staggering amounts of new scientific knowledge." Although he reportedly spoke partly in jest, the shock of such a suggestion produced considerable reaction in the United States as well and the Bishop's remark became the stimulus for debate over the "primacy of ends over means" and the moral depth of science.[53] In the 1930s, many scientists expressed their apprehension about "anti-intellectuals who wish to impose ideological or theological constraints on research,"[54] and humanists and theologians voiced their concern that science was like an engine out of control. Many of these same concerns cropped up again in the 1960s in several widely-circulated intellectual criticisms of the scientific establishment and social values, such as Herbert Marcuse's *One-Dimensional Man* (1964).

An early example of the 1960s questioning was the controversy that arose over Project Camelot.[55]

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[52] *Science, Growth and Society* (Paris, France: Organisation for Economic Co-Operation and Development, 1971).

[53] Carroll Pursell, " 'A Savage Struck by Lightning': The Idea of A Research Moratorium, 1927-37," *Lex et Scientia,* vol. 10, October-December 1974, pp. 146-158.

[54] Price, op. cit., p. 76.

[55] For more extensive discussion of Project Camelot, see *Technical Information for Congress,* report to the U.S. Congress, House Committee on Science and Technology, Subcommittee on Science, Research, and Technology, July 1979, pp. 145-179. Also see Irving L. Horowitz, "The Life and Death of Project Camelot," *Trans-Action,* November-December 1965, pp. 4-10.

In his 1961 message on the defense budget, President John F. Kennedy, motivated by the first Cuban crisis and growing instability in some developing countries, had proposed to increase the U.S. capability in dealing with "guerilla forces, insurrections, and subversion," by strengthening military resources of anthropological, cultural, and other social science data in relevant geographic regions. The result of this proposal was Project Camelot, a Department of Defense (DOD) project in applied research in the social sciences. The project would have attempted to study the political, economic, and social preconditions of instability and potential Communist usurption of power in several developing countries. Political reaction to the project, however, was strong and significantly negative. Congress opposed DOD intrusion into foreign policy and the military takeover of foreign policy research, and feared the potential damage in foreign relations with Latin American countries. Social scientists were concerned about military sponsorship of social science research and, more generally, about the relationship between the Federal Government and the social science community in the utilization of social science research and data in serving national purposes. As a result of the controversy, Project Camelot was eventually suspended.

Later in the decade, as the universities became the institutional arena for protest against the Vietnam War, some of that activity was directed against university involvement in scientific research supported by the Department of Defense. Boycotts and petitions were spearheaded by Scientists and Engineers for Social and Political Action, later renamed Science for the People. One of its founders, Charles Schwartz, described the animating beliefs of this group as a reaction to the "specific corruption of science": "Science as a whole is being abused by the powerful political, industrial and military interests, and we are all losers."[56] This political movement was strengthened when scientists at over 30 schools, following the lead of scientists at Harvard University and Massachusetts Institute of Technology, held a work stoppage for one day on March 4, 1969, interrupting their research to protest the war and the use of science for military purposes.[57] At some institutions, the result of such activities was that classified weapons research was transferred to laboratories that were off-campus and separately administered.

Concerns about military domination of academic science were not confined to campus activists and scientists. Senator William J. Fulbright proclaimed in a 1967 Senate speech:[58]

> The universities might have formed an effective counterweight to the military-industrial complex by strengthening their emphasis on traditional values of our democracy, but many of our leading universities have instead joined the monolith, adding greatly to its power and influence.

Acting on these concerns, Congress passed an amendment in August 1969 to the Defense Authorization Bill of 1970 which included language prohibiting DOD from funding basic research not directly related to a specific military function or operation. Called the "Mansfield Amendment" after Senator Mike Mansfield (D-MT), who was a cosponsor and one of its most outspoken defenders, Section 203 of Public Law 91-121 sought to realign the funding patterns for basic science:[59]

> The intent of the provision is clear. It is a mandate to reduce the research community's dependence on the Defense Department when it appears that the investigation under consideration could be sponsored more reasonably by a civilian agency. After all, the National Science Foundation was created by Congress back in 1950 specifically to channel federal funds into basic research.

Mansfield proclaimed that the amendment was "neither anti-military nor anti-research"; rather, its intention was to reinforce the role of the NSF as the "primary source" of basic research funds, because the role of DOD in sponsoring basic research was "intended to be incidental rather than predominant."[60]

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[56] Penick, et al., op. cit., p. 430.

[57] Jonathan Allen (ed.), *March 4: Scientists, Students, and Society* (Cambridge, MA: The MIT Press, 1970).

[58] David Dickson, *The New Politics of Science* (New York: Pantheon, 1984).

[59] U.S. Congress, House Committee on Science and Astronautics, Subcommittee on Science, Research, and Development, "National Science Policy," Hearings on H. Con. Res. 666, U.S. House of Representatives, 91st Cong., 2d sess., 1970.

[60] Penick, et al., op. cit., pp. 344-346. Also see Rodney W. Nichols, "Mission-Oriented R&D," *Science*, vol. 172, Apr. 2, 1971, pp. 29-37.

The direct and immediate effect of the Mansfield Amendment was not very great. It was legally in effect for only 1 year and was not renewed. Only 220 of the 6,600 research projects that were reviewed were affected by the amendment, involving a total of $8.8 million, or only 4 percent of Defense funds for academic research. In the following year, the amendment's language was changed from "direct and apparent relationship" to military needs, to "in the opinion of the Secretary of the Defense, a potential relationship."[61] Nevertheless, the Mansfield Amendment did signify a change in policy toward the support of basic science, and in the words of former Presidential science advisor, Edward E. David, Jr., "its influence has continued to be felt throughout the Department of Defense . . . [and] it has drastically reduced the willingness of many other Federal agencies to fund basic scientific work that cannot be clearly related to their current missions."[62] The amendment appears to have created a climate of greater caution and uncertainty in making research grants, not only in DOD but in other agencies.

By the 1960s, the Federal agencies were also playing an active role in shaping the Nation's environmental future, often without any clear statement of national environmental policy. The U.S. Bureau of Reclamation, the U.S. Corps of Engineers, the U. S. Department of Agriculture, the Federal Highway Administration, and similar agencies had been reshaping the landscape.[63] Their actions, however, were not always benign; some appeared to result in inadvertent, unanticipated degradation of the environment or destruction of plant or animal species, or chemical contamination of waterways. Although some of the environmental degradation may have actually been due more to deployment and expansion in the scale of old technologies, or due to actions taken to accomplish political goals, the negative effects were often blamed on science and technology.

A legislative result of this concern was the passage of the National Environmental Policy Act of 1969 (NEPA), which focused on the Federal Government's role in shaping and protecting the environment. The legislation gave a message that there was a need to anticipate environmental impact and to do some of that through research. Lynton Caldwell has observed that: "The task set for its authors was to redirect national policy toward the environment," but "the method was procedural reform," including the instigation of research.[64] In attempting to make Federal agencies accountable for "actions that significantly affected the quality of the human environment,"[65] NEPA requires Federal agencies to prepare environmental impact assessments for all major actions significantly affecting the environment[66] and it creates administrative requirements that agencies either cite research knowledge as evidence for decisions or, as necessary, commission and conduct research of their own. NEPA, Title I, Section 102 mandates agencies to "utilize a systematic, interdisciplinary approach which will insure [sic] the integrated use of the natural and social sciences and environmental design arts in planning and decisionmaking."[67] One of the responsibilities of the Council on Environmental Quality created by NEPA was "to conduct investigations, studies, surveys, research, and analyses relating to ecological systems and environmental quality."[68] The Council on Environmental Quality later specified in new regulations that "if scientific uncertainty exists but can be cured by further research, the agency must do or commission the research."[69] In recent years, the courts have taken a more active role in requiring the agencies to fulfill this mandate.

The increased environmental regulation of industry—as well as other social legislation—had a number of unplanned effects on the scientific research system.* In the late 1960s and early

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[61] Dickson, op. cit., p. 122.

[62] Edward E. David, Jr., "The Federal Support of Mathematics," *Scientific American,* vol. 252, May 1985, p. 45.

[63] Lynton K. Caldwell, *Science and the National Environmental Policy Act: Redirecting Policy Through Procedural Reform* (University, AL: The University of Alabama Press, 1982), p. 8.

[64] Ibid., p. 9.

[65] Ibid.

[66] Mark Reeve, "Scientific Uncertainty and the National Environmental Policy Act—The Council on Environmental Quality's Regulation 40 CFR Section 1502.22," *Washington Law Review,* vol. 60, No. 1, 1984-1985, p. 101.

[67] Caldwell, op. cit., p. 12.

[68] National Environmental Policy Act, Title II, Section 205(5).

[69] Reeve, op. cit., p. 101.

*To be discussed in more detail in ch. 5.

1970s, Congress created the Environmental Protection Agency, the Occupational Safety and Health Administration, the National Highway Safety Commission, the Consumer Product Safety Commission, the Mining Safety and Enforcement Administration, and the Equal Employment Opportunity Commission. In addition, the jurisdiction and enforcement powers of several existing Federal agencies (such as the Federal Trade Commission) were expanded. This explosion in protective regulation can be attributed to many things, such as changes in the underlying technology of industry or changes in perception about what constitutes potential risk, combined with increasing awareness and growing intolerance of risks. Traditional protections, especially market and liability laws, seemed inadequate to encourage socially responsible behavior. Moreover, the scientific research system—as it participated in the regulation—was becoming increasingly visible and more federally dependent. In addition to its use in forming regulatory policy, science was expected to comply with protective regulations and social programs originally directed at industry or the professions.

Perhaps the most significant science policy debate of the 1960s—in its long-term effects on public and political attitudes toward research and in resulting regulation—surrounded the use of human subjects in scientific experiments. The U.S. mass media had in the 1960s carried a number of reports about unsavory situations—here and abroad—in which prisoners, children, the poor, and the elderly were exposed to unwarranted risks in the name of "experimentation." The issue was politically volatile, and it touched on fundamental questions of who should set the standards for control of scientific research. In a 1966 article that captures the spirit of that debate, Henry K. Beecher wrote:[70]

> . . . it is absolutely essential to *strive* for [informed consent to experimentation] for moral, sociologic and legal reasons. The statement that consent has been obtained has little meaning unless the subject or his guardian is capable of understanding what is to be undertaken and unless all hazards are made clear. If these are not known, this, too, should be stated. In such a situation the subject at least knows that he is to be a participant in an experiment. . . . Ordinary patients will not knowingly risk their health or their life for the sake of "science."

Prior to 1963, investigational or experimental new drugs, for example, could be used in research involving human subjects if the drugs were labeled and intended solely for investigational use.[71] The Food and Drug Administration (FDA) had no direct control over the drugs, the investigators, or the research to be done; "there was no requirement that a patient be told that he or she was to receive an investigational drug."[72] That autonomy changed in 1963 when FDA, in response to the 1962 Drug Amendments (known as the Kefauver-Harris Amendments), issued Investigational New Drug regulations requiring that "any person or manufacturer seeking to study a new drug in human subjects . . . prepare and present to the FDA an acceptable plan for the investigation."[73] In 1966, the U.S. Public Health Service began to require all institutions (e.g., universities, commercial laboratories) to which it made grants to establish boards to review investigations involving human beings: ". . . to safeguard the rights and welfare of research subjects, to ascertain whether the methods used to gain their consent were appropriate, and to evaluate the risks and benefits of the experiment."[74] One analyst has characterized events of this time as the "legalization of ethical choices."[75] By the early 1970s, several legislative and administrative actions had attempted to implement such safeguards. Requirements for institutional review of research involving human subjects had gone from a matter of agency policy to one of Federal law. The institutional review boards required for each institution receiving Department of Health and Human Services (DHHS) funds became the principal means for enforcing national political and social expectations. The legislative intent, however, was to require the researchers and the grantee institutions to self-regulate so that detailed Federal Government regulations might not be necessary.[76]

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[70] Henry K. Beecher, "Ethics and Clinical Research," *The New England Journal of Medicine*, vol. 274, June 16, 1966, p. 1360.

[71] Alexander M. Schmidt, "The Politics of Drug Research and Development," *The Social Context of Medical Research*, Henry Wechsler (ed.) (Cambridge, MA: Ballinger Publishing Co., 1981), p. 243

[72] Ibid.

[73] Ibid., p. 253.

[74] Stanley Joel Reiser, "Human Experimentation and the Convergence of Medical Research and Patient Care," *Annals of the American Academy of Political and Social Science*, vol. 437, May 1978, p. 18.

[75] Frank P. Grad, "Medical Ethics and the Law," *Annals of the American Academy of Political and Social Sciences*, vol. 437, May 1978, pp. 19-36.

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[76] Dael Wolfle, Emeritus Professor, Graduate School of Public Affairs, University of Washington, personal communication, 1985.

THE "LIMITS TO INQUIRY" DEBATE

These various controversies, protests, and political debates took their toll on both the complacency and the autonomy of the scientific community. And in the 1970s, many researchers themselves became actively engaged in an intense debate revolving around social accountability and the acceptability of limits on scientific inquiry. The 1960's "human subjects" debate was by no means resolved and had stimulated regulation of research procedures at both the Federal and State levels. Advances in molecular biology raised new questions about the risks of genetic manipulation. Social surveys of public opinion were showing that the American people did not have an unqualified faith in science and were willing to support some controls on the research process. And, finally, general political calls for increased fiscal accountability in government accounting led some politicians to focus attention on shortcomings in the research grants and contracts system. These and many other issues and controversies became the fodder for discussions throughout the scientific community—in journals and at meetings—about science's social responsibility, about ethical behavior of researchers, and about the appropriateness of limitations on scientific inquiry.

A central focus for one of the debates was how to balance the potential risks and benefits of the "new" biology. The controversy was heightened by two factors: the rapidity of advances in the research, and the connections—often pointed out by the researchers themselves—between the potential applications of the research and public policy. When, for example, a research team at Harvard Medical School successfully isolated a human gene in 1969, a scientific frontier with unusual potential had been extended, but biologists on that team also recognized that misuse of the techniques of genetic manipulation would be undesirable. A member of the team, Jon Beckwith, in fact, publicly voiced his concern over undesirable side effects. As molecular biologists began to develop exciting laboratory techniques for manipulating and recombining DNA across species barriers, more and more biologists began to discuss the potential outcomes. These discussions led to a dramatic example of self-regulation by the scientific community.

In 1973, immediately following a major research conference, biologists Maxine Singer and Dieter Soll wrote a letter to *Science*[77] in which they appealed to the National Academy of Sciences to establish a committee to study various problems of recombinant DNA research and to recommend specific actions or guidelines in the light of potential hazards.[78] That committee recommended the instigation of a voluntary moratorium on certain forms of rDNA research and the formation of what later became a national committee to review proposals for research using these techniques, the NIH Recombinant DNA Molecule Program Advisory Committee, organized in 1974. Molecular geneticists who voluntarily imposed the moratorium asked others in the world to do likewise. Fears that flaws in these techniques might allow ecological disaster or create "new diseases" were also the impetus for proposals for regulation at State and local levels.[79] In February 1975, however, an international group of biologists, meeting at the Asilomar Conference Center in Pacific Grove, California, agreed that the voluntary moratorium be lifted and that future research be conducted under a set of rigid guidelines to be developed by the NIH Advisory Committee.

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[77] "Letters to the Editor," *Science*, vol. 181, Sept. 21, 1973.

[78] Daniel Callahan, "Recombinant DNA: Science and the Public," *Hastings Center Report*, vol. 7, April 1977, p. 20.

[79] Judith A. Johnson, "Regulation of Recombinant DNA Products," Issue Brief 85090, Library of Congress, Congressional Research Service, Science Policy Research Division, Apr. 3, 1984; and Sheldon Krimsky, *Genetic Alchemy: The Social History of the Recombinant DNA Controversy* (Cambridge, MA: The MIT Press, 1982).

The justification for that moratorium—and for subsequent regulation of the research—is discussed in chapter 3, but it is important to emphasize that, in this case, researchers were generally supportive of formal government commissions and legislation; most accepted some regulation as inevitable and realized the importance of shaping the controls to fit their research needs. There was also relatively little public input to the early stages of the debate.[80] The result of the national scientific debate and congressional attention was the implementation in 1976 of a National Institutes of Health document *Guidelines for Research Involving Recombinant DNA Molecules,* which: 1) imposed restrictions on the types of experiments that might be performed at NIH grantee institutions, and 2) specified minimum levels of physical and biological containment for permissible recombinant DNA experiments. In 1977, in compliance with the National Environmental Policy Act, NIH adopted an environmental impact statement for the 1976 *Guidelines*.

At about this same time, a number of public opinion surveys appeared to be indicating a decline in the public's traditionally high support for and confidence in science.[81] (See app. B for a general discussion of public attitudes toward science.) Some survey data indicated that more and more non-scientists were inclined to question science's traditional autonomy or to express a lack of confidence in science's ability to solve social problems through research. People seemed to confuse science with technology, and to see science "in a very technological, instrumental light."[82] As a part of its new *Science Indicators* series, the National Science Board (NSB) decided to include a chapter on public attitudes toward science. Using data from Opinion Research Corporation surveys in 1972, 1974, and 1976, the chapters of the NSB reports described a public that, although still holding science and technology in high regard, was much less supportive than it had been in 1957, the date of the last previous comprehensive survey. While 90 percent of the public thought that the world was "better off" because of science in 1957, only 70 percent of the public held the same view in 1972.[83] Similar results were obtained in the 1974 and 1976 studies.[84] The percentage of those willing to say that the world was worse off because of science did not increase significantly, but the percentage of persons who were uncertain, undecided, or felt that things were about equal did increase substantially over the 15-year period spanned by the four studies.

In a 1979 national study also sponsored by the National Science Board, several of the 1957 questions were repeated, offering an opportunity for comparison across two decades. In 1979, 81 percent of the public still agreed that scientific discoveries were making their lives "healthier, easier, and more comfortable" and 86 percent expressed the view that scientific discoveries were "largely responsible" for the standard of living in the United States.[85] In a comparable national study in 1983, Jon D. Miller found that 85 percent of American adults continued to agree that science made their lives healthier, easier, and more comfortable.[86] Contradictory evidence, however, was provided by other surveys sponsored by NSB, which had asked respondents to assess the relative benefits and harms of science and to weigh the two.

The data from the 1970s thus indicated that although only about one in 20 Americans believed that science does more harm than good, about one-third were not sure where the balance fell. Some of this uncertainty may have reflected a wary attitude toward science; some may have been due to a lack of interest or information. In the 1970s "limits of inquiry" discussion, however, the scientists found the potential "wariness" frightening.

If there was a significant change in public opinion, why did it occur? Some argue that respect for scientists diminished because the scientific establishment became "identified with the general power structure"; others believe that it was because of "an exchange of roles between science and religion in relation to the stability of the prevailing political system."[87] Some senior scientists, unaccustomed to public criticism, sincerely believed at the time that scientific values and traditions were under serious attack.

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[80] Callahan, op. cit., p. 20.

[81] Amitai Etzioni and Clyde Nunn, "The Public Appearance of Science in Contemporary America," *Daedalus*, vol. 103, summer 1974, pp. 191-206.

[82] Ibid., p. 203.

[83] *Science Indicators—1972* (Washington, DC: National Science Board, 1973).

[84] *Science Indicators—1974* (Washington, DC: National Science Board, 1975); and *Science Indicators—1976* (Washington, DC: National Science Board, 1977).

[85] Jon D. Miller, et al., *The Attitudes of the U.S. Public Toward Science and Technology* (Washington, DC: National Science Foundation, 1980).

[86] Jon D. Miller, "A National Survey of Adult Attitudes Towards Science and Technology in the United States," Annenburg School of Communications, University of Pennsylvania, Philadelphia, 1983.

Many linked the change to science's new status as a visible target in the Federal budget. Congressional attitudes—which were moving away from relatively unquestioning support—may have been influenced by the social discussion. Some criticism was undoubtedly prompted by the scientists' own doubts about "the omnicompetence of science in human affairs." But political scientist Don K. Price speculated in 1972 that the politicians' questioning resulted most "from the normal disposition of anyone who lends or grants money to want to know what use is being made of it, and whether the terms of the bargain are being kept."[88]

Such normal policy questions received widespread publicity when, in 1975, Senator William Proxmire (D-WI) launched an unprecedented attack against National Science Foundation funding of social science research. Proxmire, then Chairman of the Senate Appropriations Subcommittee that reviews the NSF budget, established the "Golden Fleece of the Month" awards to illustrate what he regarded as examples of waste in the government—occasionally attacking projects that he asserted "at best, of nominal value to the American taxpayer." Scientists, angered at the attack, countered that projects with obscure titles and subjects may nevertheless deal with relevant and important problems. They feared a dangerous precedent if immediately applicable science was perceived to be the only worthwhile science.

The political momentum of the "Golden Fleece" awards was eventually slowed when a behavioral scientist who had received such an award filed suit against Proxmire, arguing that, as a result of Proxmire's actions, he had suffered a loss of respect in his profession, was "held up to public scorn, and suffered a loss of income and ability to earn income in the future." A Federal district court in Madison, Wisconsin, granted a summary judgment in Proxmire's favor on the grounds that he enjoyed absolute immunity under the Speech and Debate Clause of the Constitution; but in 1979 the Supreme Court held that the researcher was not a public figure simply by virtue of receiving Federal funding, and that congressional immunity did not extend to statements made outside Congress.

Despite a lessening of political criticism following the Supreme Court decision, the scientific community reacted as if the integrity of all science in general had been questioned. Many researchers seemed to be underestimating the demand for accountability inherent in acceptance of public funding.[89] "Those [scientists] who came of age during the fifties and sixties," Robert S. Morison observed in the 1970s, "may never quite understand why they have suddenly become 'accountable' to a 'participatory democracy'."[90]

Insensitivity may not be the entire explanation, however, for public perceptions of science in general were also changing. Only a decade before, science had had unquestioned social authority in the culture and its research funding was ample, growing, and relatively easily acquired; by the 1970s, research was being conducted in a social climate that admitted scientific authority to questioning and in which other demands were biting into science's portion of the Federal budget. Scientists who had been trained before the war probably also could not have imagined the extent of regulation of the research process which had begun to occur.

Some scientists who took part in these discussions reacted negatively to the proposal of citizen participation in what were traditionally considered to be "scientific" matters.[91] "How," one commentator asked, "can public participation be arranged without clashing with the very meaning of science as a consensual activity among trained specialists?"[92] Scientists who had previously assumed total control over their research now talked about being at the "mercy of citizens' groups" who were seeking input to the decision-making process.[93]

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[87] "Limits of Scientific Inquiry," *Daedalus,* spring 1978, p. vii.

[88] Price, op. cit., p. 80.

[89] Robert S. Morison, "Commentary on 'The Boundaries of Scientific Freedom'," *Newsletter on Science, Technology, & Human Values,* June 1977, pp. 22-24.

[90] Ibid., p. 24.

[91] "Limits of Scientific Inquiry," op. cit., p. viii.

Despite this reaction—or perhaps because of it—many leaders of the scientific community appear to have believed that public scrutiny inevitably implied restrictions. According to Dorothy Nelkin, by the 1970s, it was no longer a question of *whether* there would be public control, but of who would participate, how control would be organized, and how much they would influence research decisions.[94] The discussions then moved to consideration of how the situation could be shaped to "protect" basic science, and to when and how much the public representatives would actually be involved.[95]

The scientists, philosophers, and policy analysts were not, however, always in agreement about the question under debate. Some regarded it as a debate over "limits to free scientific inquiry," viewing proposed regulation as an attempt to inhibit researchers' freedom to pursue intellectual inquiry. Others began to frame the debate in terms of funding priorities. André Hellegers once made this point forcefully, arguing that freedom of inquiry was *not* under assault because science was, in fact, "royally" funded.[96] Hellegers cited the two central issues for science as: 1) "Given finite resources, how much should the public invest in an enterprise such as science?; and 2) "How far (if at all) should any enterprises, in the name of freedom of inquiry, be allowed to infringe on the freedom of others?"[97] Should low priority be given to those activities that have adverse consequences?[98] To Hellegers, the real topic of importance was "the ordering of priorities in things which affect both science and human values."[99]

Don K. Price has observed that in the 1970s scientists were often inclined to blame their problems on politicians. This tendency was exacerbated by historic differences in the outlooks of the two groups. Scientists and politicians operate in different time frames—Congress in the short term and scientists in the long term. Conflicts often arise from the imposition of a political paradigm onto the agenda of the scientific community. But Price believes that the problems themselves evolved from three other factors. First, the political strategy for the support of science was devised by scientists themselves and was based on the experience of private philanthropy before World War II. Second, the political authorities had accepted science "as the dominant intellectual approach to public issues, which scientists and other liberal intellectuals agree must therefore be regulated in the public interest." And third, the U.S. constitutional structure is "too decentralized to sustain the integrated and long-term view of public policy which might justify the support of science as an intellectual and educational enterprise."[100]

The academic debate over "limits to scientific inquiry" can be seen as a response to social pressures, to events and progress within science, and to the scientists' fear that public support for science was declining. The academic scientific community believed that it was necessary to defend the very core of science—which they perceived as under attack. They saw the humanists' criticism and the attempts to regulate as threats to the legitimacy of modern science.

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[92] Ibid., p. 232.

[93] Ibid., p. viii.

[94] Dorothy Nelkin, "Intellectual Property: The Control of Scientific Information," *Science*, vol. 216, May 14, 1982, p. 207.

[95] André Hellegers, "The Ethical Dilemmas of Medical Research" and Barry Casper "Value Conflicts in Restricting Scientific Inquiry," *Regulation of Scientific Inquiry*, Keith M. Wulff (ed.) (Boulder, CO: Westview Press, 1979).

[96] Ibid., p. 9.

[97] Ibid., p. 11.

[98] Ibid., p. 22.

[99] Ibid., p. 29.

[100] Price, op. cit., p. 76.

RECENT RESTRICTIONS ON SCIENTIFIC COMMUNICATION

From the earliest days of the Nation, Federal policy has largely been supportive of open communication, free exchange of information, and wide publication in scientific research.[101] From time to time, however, recognition has been given in Federal law to "circumstances that constitute what have been thought to be obvious and compelling reasons for imposing official secrecy on research or restrictions on the dissemination of certain kinds of research findings."[102] For example, the first War Powers Act, signed 11 days after Pearl Harbor, gave the President the authority to censor all communications with foreign countries. But the scientific community has also made some attempts at voluntary control. In 1940, for example, editors of various professional journals cooperated with a special committee of the National Research Council to review papers for possible defense information.[103] This combination of Federal support for open communication, defense-related restrictions imposed on a case-by-case basis, and occasional voluntary cooperation by the scientific community continues today.

Because of this history, it is noteworthy therefore that the most controversial regulatory issue for science in the 1980s has been the imposition of restrictions on the communication of basic science. In part, the new restrictions have resulted from the changing nature of information, especially its status as a valuable property or national commodity, and from the growth in modes of dissemination of information. The decreasing distinction between basic and applied research added to the difficulty of assigning national security classification according to the information's potential for application. And, especially in the last few years, there is an increased perception that the export of U.S. technology is weakening this country politically and economically on a worldwide basis.[104]

This series of disputes first arose in the late 1970s, when the National Security Agency (NSA) and later the National Science Foundation attempted to prevent university-based cryptology researchers from publishing their unclassified work on encryption schemes. In these cases, the Federal Government invoked the Invention Secrecy Act and the International Traffic in Arms Regulations, regulations intended to control the export of munitions and related technology. The result of discussions between the universities and the government was the adoption of a voluntary prepublication review process, under which copies of manuscripts on cryptology are sent to NSA at the same time they are circulated to colleagues or submitted to journals.[105] This system of voluntary prior restraint was endorsed in 1980 by the American Council on Education, and in 1981, NSF amended its policies on research grants to require similar prior restraint on "potentially classifiable results."[106]

At about the same time, the Department of Defense—concerned especially about the leak of information on Very High Speed Integrated Circuits—began to use the Export Administration Regulations to restrict public communication of results and to control the access of foreign scholars to U.S. university research.[107] The presidents of five major universities objected to these restrictions and to the trend of increased control that they represented. That protest and the prior debate over restrictions on cryptology research were principal factors in the initiation of a special National Academy of Sciences-National Academy of Engineering-Institute of Medicine panel, under the direction of Dale Corson, which issued its seminal report "Scientific Communication and National Security" in 1982.[108] The Corson panel report has been a touchstone for subsequent reaction to government actions to restrict scientific and technical communication.

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[101] Harold C. Relyea, "Shrouding the Endless Frontier—Scientific Communication and National Security: The Search for Balance," *Striking a Balance: National Security and Scientific Freedom,* Harold C. Relyea (ed.) (Washington, DC: American Association for the Advancement of Science, 1985), p. 75.

[102] Ibid.

[103] Harold C. Relyea, "Increased National Security Controls on Scientific Communication," *Government Information Quarterly,* vol. 1, No. 2, 1984, pp. 187-188. See also Michael M. Sokal, "Restrictions on Scientific Publication," *Science,* vol. 215, Mar. 5, 1982, p. 1182; and Michael M. Sokal and Janice F. Goldblum, "From the Archives," *Science, Technology, & Human Values,* vol. 10, spring 1985, pp. 24-27.

[104] *Interim Report of the Committee on the Changing Nature of Information* (Cambridge, MA: Massachusetts Institute of Technology, Mar. 9, 1983).

[105] John C. Cherniavsky, "Case Study: Openness and Secrecy in Computer Science Research," *Science, Technology, & Human Values,* vol. 10, spring 1985, pp. 99-104.

[106] See sec. 794 on National Security in the NSF Grant Policy Manual.

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[107] Ibid., p. 102.

[108] *Scientific Communication and National Security*, report by the Panel on Scientific Communication and National Security Committee on Science, Engineering, and Public Policy (Washington, DC: National Academy Press, 1982).

POLITICAL INFLUENCES ON REGULATION

The science policy developed over the last 40 years reflects certain assumptions about the nature of science, the character of scientists, and the political management of science. There have been important assumptions about the ability of scientists to govern their own affairs; often, discussion of the peer review system will figure prominently as evidence of whether or not this governance "works." Other assumptions are made about whether, given the current structure of science, effective and equitable regulation is possible; and related to that are a host of assumptions about the nature of expertise—especially the belief that, on scientific matters (even those with heavy policy components), scientists alone can best identify promising projects and areas of research. Historian Alex Roland, in his March 7, 1985, testimony to the Science Policy Task Force of the House Committee on Science and Technology, articulated this perspective well when he observed that "scientists understand nature's laws better than anyone else; they are in the best position to see the potential applications of their undertaking."

Some assumptions relate to the conduct of research—such as where it is best performed—or to the appropriate relationship between research and university education. Other assumptions relate to the process of regulation. There are, for example, strong opinions about how far government "interference" should extend in all aspects of science policy and about who should participate in the development of policy about controls. Assumptions about who should control research and at what stage are also inextricably linked to the question of who is the best judge of science, who is the expert, and who evaluates science.

How are changes in these assumptions—and in the social relations of science—affecting the intensity and extent of the regulatory environment for research?

Without doubt, there is new pressure for a balance between the push for scientific and technical progress and the demand for regulation. Congressional management of science and technology today may require special legislative effort to reconcile the complexity and sophistication of new technological challenges with society's regulatory capabilities.

Another important force shaping enforcement of Federal regulation on scientific research is a national fear of failure, especially in international technological competitiveness. Science policy leaders argue for increased funding in order to keep the United States from "falling behind" in certain scientific fields. But these same arguments are used by the executive branch to justify increased restrictions on scientific communication. Such attitudes have repercussions on scientific research through the setting of national research priorities and through pressures to achieve competitive status (or to "maintain the lead") in all areas of science.

One of the most visible changes—to be discussed in chapter 4—is in the creation of specific political or bureaucratic mechanisms for implementation of social controls on research. As a handle for enforcing regulation, the requirement for financial accountability inherent in the research system has been successful. The post-war contract between scientists and government had allowed the scientists, through the process of peer review, to make decisions about the allocation of government funds to specific projects but required the universities to be accountable financially to the government. Thus, regulatory requirements—committees to review research for ethics, regulations on the disposal of hazardous materials—could be tied to the award and management of money.

Changes have also occurred in the amount and type of public participation in decisionmaking on issues related to science and technology. Changes in public beliefs about the value of "expert" v. lay opinions on political or social issues involving science or technology have reinforced the trend toward less autocratic control of science by scientists. Until the last decade or so, when policymakers turned to scientists for advice in making decisions on technically-intensive public policy issues, the practice was to distinguish between the technical and the political, or normative, aspects of a problem.[109] Today, the involvement of more laypersons in that decisionmaking process on regulating research has not only shifted some control from the scientists but has introduced more sensitivity to normative concerns.

These and other influences on U.S. research have helped to change the nature and character of the politics within which research is conducted. When the Bush and Steelman reports outlined their visions for how the Federal Government should sponsor and finance a national structure for scientific research, there was little reason to believe that those same arrangements could become the vehicles through which research might be regulated according to prevailing social or political attitudes. Science was to be managed with loose reigns. It was not perceived as either requiring suspicious administration or warranting externally-imposed controls. The specific links between the events that stimulated much of the current regulation and the concurrent shifts in public attitudes are not well understood, but it is clear that, in the 40 years since Bush, something has changed. That shift is linked in some way to the original assumption that guided the design of the system as well as to the assumptions that now underpin priority-setting and funding today. Science is now clearly conducted within a regulatory environment that affects its agenda, its procedures, and its communications. The next four chapters describe the existing situation—why regulation occurs, how it occurs, and where it occurs.

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[109] Loren R. Graham, "Comparing U.S. and Soviet Experiences: Science, Citizens, and the Policy-Making Process," *Environment*, vol. 26, September 1984, p. 8.

Chapter 3

Social and Political Rationales for Controls on Research

Photo credit: National Institutes of Health

Chapter 3

Social and Political Rationales for Controls on Research

Harold Green has observed that, all things being equal, there is no question that "a scientist has the freedom to think, to do calculations, to write, to speak and to publish"—as long as these activities remain within the area of abstractions.[1] Research, of course, involves more than abstract thinking. Scientists experiment, observe subjects, record data, and describe their work to others. These activities can be affected by social mores and customs and can in turn affect society, the environment, or the people and objects involved in the research. When research violates the social norms, or when society perceives risks or dangers in the research process, then restrictions may be implemented either by society or voluntarily by the research community.

This chapter develops a typology of the various reasons used to justify either legally enforceable regulations or social restraints on scientific activity. In most cases, the rationale described is one that is used to explain why scientists should not do research on a certain topic or in a certain way, or should not describe their results to a particular group of people. In a few instances, the justification may be used to discourage scientists from pursuing one research line or encourage them to pursue another, or to protect government or commercial rights in scientific information.[*]

This chapter describes the rationales or legal justifications for two types of regulation of scientific research. One type includes legal barriers, incentives, or other actions that have some binding or controlling effect. The other type of regulation includes forces or actions—ranging from changes in funding to negative public opinion—that do not have the force of law but may have some important effects because of the way in which science is funded and is dependent on political and social support for the continuation of that funding.

Table 3-1.—Justifications for Control of Research

Regulatory forces on the research agenda:
- To fulfill political objectives
- To avoid environmental damage
- To promote or avoid specific economic consequences
- To preserve moral values

Regulation of research procedures and protocols:
- To protect human health and safety
- To protect animals used in experimentation
- To protect the environment

Regulation of the dissemination of scientific knowledge:
- To uphold scientific standards
- To protect a professional or economic interest
- To protect the health, privacy, and safety of individuals
- To protect the national military or economic security

REGULATORY FORCES ON THE RESEARCH AGENDA

Attempts to control the research agenda of a field or laboratory may take one of two forms. Opponents of a research topic may wish to suppress a project or a line of research because they are convinced that application of the research could bring harm. Others may be unwilling to grant legitimacy to a morally (or politically) objectionable idea by implying that it is worthy of scientific attention. Proponents of a research topic may seek to alter the research agenda to include that topic.

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[1] Harold P. Green, "The Boundaries of Scientific Freedom," *Regulation of Scientific Inquiry,* Keith M. Wulff (ed.) (Boulder, CO: Westview Press, 1979), p. 140; reprinted from *Newsletter on Science, Technology, & Human Values,* June 1977, pp. 17-21.

[*] Issues or events are described in this chapter as examples of when a particular justification or rationale may have been employed. A scientific topic or project may have been regulated for more than one reason, but all these reasons are not necessarily listed for each example.

For these reasons, justifications are likely to be affected by beliefs about the probability and type of any eventual application. The regulator is convinced that, should the research ever be done, some imaginable (or predictable) result or finding would be unacceptable or undesirable. The potential of research for application—and the regulator's ability to envision such application—thus can have considerable effect on the predisposition to control. Harvey Brooks points out, "the regulatory climate for research which is influenced by its potential applications will depend on the uniqueness of the relation of these applications to the substantive content of the research, since the amount and richness of the applications vary considerably among types of research."[2] Some observers, however, argue that all regulation occurs because of the anticipation of some effect, although they may distinguish between attempts to limit inquiry because of: 1) "anticipated deleterious consequences of the inquiry itself" (e.g., effects of the research procedure on experimental subjects); and 2) "anticipated deleterious consequences of applications of knowledge obtained by the inquiry."[3]

The most common justifications for restraints on research agenda are political, environmental, economic, and moral concerns.

To Fulfill Political Objectives or Avoid Political Effects

Political reasons may underlie both the encouragement and the suppression of research, when society perceives that research could achieve a specific advantage or result in a negative effect. The *protection of national economic or military security,* for example, may justify either the redirection of research toward military goals or the inhibition, discouragement, or prohibition of weapons development research outside of government control. Both justifications were used during the 1970s controversy over research on the laser separation of isotopes of uranium. That research topic became an active area of controversy in 1976, when experiments in both government and private industry labs showed a promising new approach to laser isotope separation. A few months later, a private consortium, Jersey Nuclear-Avco Isotopes, Inc. (JNAI) applied to the U.S. Nuclear Regulatory Commission for a license to build a $15 million facility for large-scale experiments using one of these approaches.[4] Because laser isotope separation was believed to promise a cheaper, easier way to obtain enriched uranium—for both nuclear powerplants and weapons—these new developments provoked both considerable controversy and attempts to classify the work. Many observers believed that existence of a perfected process would increase the risk of unintentional proliferation of nuclear weapons, would undermine existing international safeguards, and could aid terrorists. In proposing a moratorium on further research and development, physicist Barry Casper argued that "there is still time to stop and consider whether laser enrichment *should* be developed, in light of its broader consequences."[5] Proponents of the research argued that laser isotope separation required sophisticated facilities and was not a "garage" technology adaptable by terrorists, and that therefore those fears were groundless.*

At the international level, the nuclear nations have tried to curb the proliferation of nuclear weapons by preventing additional countries—and especially countries considered to be politically unstable—from doing nuclear research that could produce weapons-grade plutonium. International political objectives have also justified government actions that discouraged or denied permission to foreign students from certain countries who wanted to study nuclear engineering in the United States. By preventing access to advanced training in certain fields, the United States was effectively attempting to control the other country's research agenda.

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[2] Harvey Brooks, Benjamin Peirce Professor of Technology and Public Policy, Harvard University, personal communication, 1985.

[3] Barry M. Casper, "Value Conflicts in Regulating Scientific Inquiry," *Regulation of Scientific Inquiry,* Keith M. Wulff (ed.) (Boulder, CO: Westview Press, 1979), p. 15.

[4] Barry M. Casper, "Laser Enrichment: A New Path to Proliferation?" *Bulletin of the Atomic Scientists,* January 1977, p. 29.

[5] Ibid.

*In fact a special panel of consultants appointed by JNAI concluded that the JNAI process was probably less proliferation-prone than the centrifuge process which was being commercialized, or than the process being developed at Los Alamos.

National economic priorities and international standing may justify redirecting research toward topics related to technological competition. When a country decides to shore up its prestige in the international scientific community, it often concentrates on achieving or maintaining superiority in some but not all scientific fields. Such justifications may be discerned in, for example, the current debate on funding high energy physics and the superconducting supercollider. Belief that the success of U.S. industry in competing in world markets is increasingly tied to research has prompted several regulatory actions in the field of biotechnology. In 1984, for example, the Cabinet Council on Natural Resources and Environment asked 14 agencies to develop a framework for the regulation of gene splicing.[6] George Keyworth, President Reagan's Science Advisor, has also suggested that the National Institutes of Health should broaden its mission by paying more attention to the needs of the biotechnology industry through more funding of generic applied work in biotechnology, promotion of intellectual support for biotechnology companies, and training of bioprocess engineers and other needed personnel.[7] International relations may also affect research when science and technology are used as tools for political diplomacy, as in scientific exchange programs.

Government actions may also be directed at encouraging or discouraging research related to *specific domestic political goals*. During the Reagan Administration, the regulatory system itself has been used to influence the funding of research pertaining to specific regulatory issues. Executive Order 12485 (Jan. 4, 1985) instituted an Office of Management and Budget (OMB) review of regulation-related research proposed by executive branch agencies. Through its power to approve the appearance of any research on the regulatory calendar, OMB can control the agencies' research agenda *before* funding. In the late 1960s, both domestic and international politics related to U.S. involvement in the Vietnam War shaped a number of acrimonious debates over whether universities should accept Department of Defense funding.[8]

Special difficulties arise when the justifications for control are linked to a *controversial social or political issue*. Various forms of research to detect XXY and XYY chromosomal aberrations, such as the screening of male newborns to identify and study prospectively the development of those with a XYY karyotype, combine basic epidemiological research with longitudinal followup of "experimental" (XYY) and "control" groups, including potential therapeutic intervention.[9] In the mid-1970s, at Harvard Medical School, objections by Harvard University faculty members and by geneticists elsewhere in the Boston academic community resulted in the voluntary termination of a research project on XXY and XYY children.[10] The project staff argued that research should proceed because of its potential therapeutic value to the patients. They were sincerely attempting to advance science and "to bring what they perceived as the benefits of science to the resolution of a social problem."[11] Their opponents, with equal sincerity, sought to expose and stop what they perceived as a "misuse or abuse of scientific hypotheses and techniques."[12] Scientists critical of the research topic argued that there was no scientific evidence linking XYY and antisocial behavior,[13] and that the research should be stopped because its goals directly contradicted American political beliefs about the rights of individuals. Other critics believed that the research had the potential of being just the first step in an attempt to determine a genetic basis for antisocial behavior. Infants tagged as having such a trait might be treated differently all their lives and therefore identification might become a self-fulfilling prophecy.[14] And finally, some asserted that the research should be stopped because the benefits to society were dubious.[15] Defenders of the research called this latter argument "a misplaced ideological approach."[16] In this case, both proponents and opponents had to weigh the importance of protecting the rights of individuals against the importance to society of predicting (and therefore possibly preventing) criminal behavior, the importance to future generations of developing chromosome screening for the detection of genetically linked illnesses,[17] and the importance to current patients should reliable therapy ever become available.

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[6] An Administration official was quoted as saying that the framework was aimed at avoiding "federal actions that could affect the industry's competitiveness." *Business Week*, May 21, 1984, p. 40.

[7] Barbara Culliton, "NIH Role in Biotechnology Debated," *Science*, vol. 229, July 12, 1985, pp. 147-148.

[8] Dorothy Nelkin, *The University and Military Research: Moral Politics at MIT* (Ithaca, NY: Cornell University Press, 1972).

[9] Dorothy Nelkin and Judith A. Swazey, "Science and Social Control: Controversies Over Research on Violence," Report No. 1979, conference proceedings, Institute for Studies in Research and Higher Education, Norwegian Research Council for Science and the Humanities, p. 5.

[10] Barbara J. Culliton, "XYY: Harvard Researcher Under Fire Stops Newborn Screening," *Science*, vol. 188, June 27, 1975, pp. 1284-1285; Frederick Hecht, "Biomedical Research: Ethics and Rights," *Science*, vol. 188, 1975, p. 502; and Loretta Kopelman, "Ethical Controversies in Medical Research: The Case of XYY Screening," *Perspectives in Biology and Medicine*, winter 1978, pp. 196-204.

[11] Nelkin and Swazey, op. cit., p. 211.

[12] Ibid.

[13] Culliton, "XYY," op. cit., p. 1,284.

Political concerns can also drive the research agenda when an individual or a group of researchers attempt to redirect the agenda of an institution or a field away from one topic and toward another considered to be more socially or politically acceptable. Most often, such actions occur at the individual or personal level; but on occasion there have been loosely coordinated actions by groups. In the 1950s, for example, the Society for Social Responsibility in Science and the Committee for Social Responsibility in Engineering "required their members to take a pledge upon joining the organization which stated that they would not engage in research for destructive purposes."[18] In the 1960s and 1970s, many scientists switched fields rather than work on topics connected to weapons or to the military. Some attempted to choose research topics that they considered to be more socially relevant or more expressive of their own moral or political philosophy. Some rejected certain topics out of protest (again, on moral or political grounds) to U.S. military action in Southeast Asia or because they espoused general pacifist objections to their country's military research agenda. Decisions to reject a line of research were, however, more often related to the proposed military sponsorship of the research than to any specific application of the particular investigation. In the late 1960s and early 1970s (as discussed in ch. 2), during controversy over the presence of classified military research on university campuses, for example, the organization Scientists and Engineers for Social and Political Action actively attempted to persuade researchers to forego participation in war research or weapons production.[19]

Rejection of a research line by individuals or groups can be a form of "conscientious objection in science."[20] Individuals who "draw the line" in this way may simply decide to have nothing to do with research linked to the military or, more specifically, with nuclear weapons or chemical-biological warfare. Many physicists, whose line of interest and expertise would fit them notably for the scientific task involved, justify their refusal to work on nuclear weapons research on moral grounds. More recently, a few graduate students in the field of artificial intelligence—where the proportion of Department of Defense funding is increasing—are reported to have either switched their thesis topic to one unrelated to military applications or, in an extreme case, left school or switched fields altogether.

In the 1980s, social anxiety about the nuclear arms race has had a direct effect not in inhibiting but in stimulating research. Funding for—and researchers' interest in—arms control research has increased.* Physicians, psychiatrists, and other medical professionals have encouraged and supported new research efforts on the medical consequences of nuclear war or the psychological effect of the nuclear arms race on children.

To Avoid Environmental Damage

Environmental concerns that provoke the imposition of regulation can trigger similar conflicts in values. At issue here is the narrowness of the relation of the potential application to the overall substance and goals of the research. Does regulation undertaken because of the fear of one particular application serve to deny the potential benefits to society of other possible applications perhaps not now clearly visible?[21] This justification underpins, for example, the legal action to halt deliberate release of genetically altered organisms. In a suit discussed in more detail in appendix A, the Foundation on Economic Trends has charged that the National Institutes of Health failed to evaluate adequately the environmental impact of experiments involving the release of genetically altered organisms into the environment. The plaintiffs are seeking to halt the work altogether because they are convinced that the potential long-range benefits of such research are simply not worth the potential risks to the environment.

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[14] Kopelman, op. cit., notes 11 and 13.

[15] Ibid., p. 200.

[16] Ibid.

[17] Culliton, "XYY," op. cit.; and Hecht, op. cit., p. 502.

[18] Rosemary Chalk, "Drawing the Line: Science and Military Research," unpublished manuscript, May 1983, p. 8.

[19] Ibid., p. 8; see also Colin Norman, "Classification Dispute Stalls NOAA Program," *Science*, vol. 227, Feb. 8, 1985, p. 155.

[20] Chalk, op. cit.

*For example, the International Security Program of the John D. and Catherine T. MacArthur Foundation.

[21] Brooks, op. cit.

To Promote or Avoid Predictable Economic Consequences

International competition in trade has been used to justify suspending one line of research (or to cut back on its funding) because another line appears more promising. Such a situation currently exists in the field of silicon electronics; work in that area has been so successful that research on alternative technologies has been cut back.

In another recent case, predictions of adverse economic effects alleged to result from the eventual application of research projects have stimulated protests that may yet lead to restraints. In 1980, California Rural Legal Assistance filed a lawsuit on behalf of 19 farm workers, which charged the University of California "with unlawfully spending public funds on mechanization research that displaced farm workers."[22] The plaintiffs believe that the research—intended to develop large, more efficient agricultural machines and new farm methods—would reduce the need for human labor in agriculture. They are convinced that such innovations would have an adverse economic effect on the workers displaced by machinery, on small farms, and on consumers, and therefore that public funds should not be used to support such research. Defenders of this research argue that mechanization research should continue "in order to create more desirable jobs and to keep the American fruit and vegetable industry competitive in the international economy."[23] (See app. A for further discussion.)

To Preserve Moral Values

In some instances, a society or a group within the society may perceive the very exploration of a topic (or the legitimacy granted to the topic by a serious research effort) as a threat to moral or social beliefs. That is to say, the research hypothesis contradicts the social or political beliefs of the opponents. Early 20th century attitudes to human sexuality, for example, acted to inhibit all types of research relating to sexuality, contraception, and reproduction.[24] Research was discouraged because of fear that it might encourage or condone "immoral" behavior; religious and moral leaders objected to laboratory consideration of what were considered to be private, personal matters.

Such objections continue to be raised today. In public opinion polls run in 1983, approximately one-quarter of the adult population of the United States were willing to endorse the statement that one of the "bad effects of science" is that it breaks down people's ideas of "right and wrong."[25]

On occasion, therefore, opponents of a research topic or hypothesis believe that any exploration (however well-controlled) might endanger the social cohesion of the community. Such concerns fuel contemporary objections to research that would attempt to link human intelligence to genetic inheritance. American psychometrician Arthur R. Jensen sparked a controversy in 1966 when he argued that IQ is genetically fixed.[26] Jensen proposed that social intervention aimed at boosting minority students' IQ scores—e.g., Headstart and other compensatory educational measures—were a waste of time and money. Opponents of the Jensen research are convinced that even to consider such research as scientifically legitimate and morally acceptable would be a racist act. The mere existence of the research project was perceived as an insult to members of certain minority groups. The objections can also go beyond the desire to avoid offending certain social groups. "The critics of such research," Harvey Brooks writes, "believe that the risks of political misuse of the resulting knowledge outweigh any possible social benefits."[27] In some cases, then, the principal objection may be to undesirable application of the research knowledge; the secondary objection, offense to a social or cultural minority group.

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[22] Philip L. Martin and Alan L. Olmstead, "The Agricultural Mechanization Controversy," *Science*, vol. 227, Feb. 8, 1985, p. 601.

[23] Ibid., p. 606.

[24] For a brief review of this history, see Emily H. Mudd, "The Historical Background of Ethical Considerations in Sex Research and Sex Therapy," *Ethical Issues in Sex Therapy and Research*, William H. Masters, Virginia E. Johnson, and Robert C. Kolodny (eds.) (Boston, MA: Little, Brown & Co., 1977), pp. 1-10.

[25] Jon D. Miller, *A National Survey of Adult Attitudes Toward Science and Technology in the United States* (Philadelphia, PA: Annenberg School of Communications, University of Pennsylvania, 1983).

[26] See Richard Lewontin, "Race and Intelligence," *Bulletin of the Atomic Scientists*, March 1970. Also see Arthur R. Jensen, "How Much Can We Boost IQ and Scholastic Achievement?" *Harvard Educational Review*, vol. 39, 1969, pp. 1-123.

On occasion, however, the very idea of doing such research on a taboo subject has been sufficient to warrant social regulation. This justification plays a role in the regulations promulgated by the Department of Education (ED) to implement the 1978 Amendments to Section 439 of the Federal Education Provisions Act, commonly referred to as the "Hatch Amendments" after their originator, Senator Orrin Hatch. The ED language aims to prevent specific subject matter, teaching methods, psychological tests, or educational research from being utilized or conducted without parental knowledge or consent. It would prohibit "research" designed to "reveal" such things as: political affiliations; mental or psychological problems potentially embarrassing to a student or his or her family; sex behavior and attitudes; illegal, antisocial, self-incriminating, and demeaning behavior; critical appraisals of other individuals with whom respondents have close family relationships; legally recognized privileged and analogous relationships such as those of lawyers, physicians, or ministers; or income.

REGULATION OF RESEARCH PROCEDURES AND PROTOCOLS

With the exception of protests over the use of animals, social criticism in the early 20th century was more likely to be directed at the topics than at the procedures of research. The moral and ethical concerns expressed in attempts to control how scientists conduct their research are not new, however. What is new is the raising of such concerns to the level of government action or legally enforceable regulation.

In these cases, the rationale for external control is most often that the scientific community's own safety procedures have been or are predicted to be inadequate or insufficient to prevent harm to human beings, animals, or the environment. The motivations for managing the risks inherent in the research process are straightforward: to comply with Federal, State and local laws and regulations and thereby to avoid enforcement actions or civil or criminal sanctions for noncompliance; and to comply with common law duties (e.g., to act with due care) and thereby to avoid personal injuries or environmental degradation, as well as any liability or duty to provide compensation which could arise from claims brought by the injured parties.

To Protect Human Health and Safety

By far the most visible and vocal science policy debates on regulation have been those surrounding how to protect human health and safety. Although the preoccupation with safety is a recent phenomenon, "it has taken hold so universally and absolutely that this operation hardly recognizes the possibility of a different world."[28] Regulations set by local or Federal authorities *to protect the health and safety of workers* (e.g., requirements for certain types and amounts of safety equipment for persons working with hazardous chemicals) apply with equal force to laboratories and, in some cases, may have been written specifically to apply to laboratory workers. The Occupational Health and Safety Act of 1970 (discussed in more detail in ch. 5) includes protections for research workers who might be subjected to unnecessary hazards on the job.

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[27] Brooks, op. cit.

[28] Robert L. Sproull, "Federal Regulation and the Natural Sciences," *Bureaucrats and Brainpower: Government Regulations of Universities*, Paul Seaburg (ed.) (San Francisco, CA: Institute of Contemporary Studies, 1979), p. 86.

Emotional controversy has surrounded efforts to extend special legal protections to *the human subjects of experimentation* (see box in ch. 4 for the specific regulations). Human subjects are used in all parts of science. They are used to test new forms of diagnostic procedures, treatments, or medicines. Carefully controlled clinical trials in drug research are necessary to prove effectiveness, to set dosage, and to uncover unknown side effects before drugs may be licensed for general use. Human subjects must be observed for research on mental disorders. Private industry uses them to test new consumer goods, or in research on how to make products more useful.

The types of experimental situations involving human subjects can be classified generally into four categories:

1. experiments done to test physiological states and environmental manipulation, both internal and external, in "normal" subjects;
2. studies of human performance and process—e.g., memory or vision;
3. the trial of new methods, procedures, or drugs on persons who are ill; and
4. the use of terminally ill patients to test potentially dangerous drugs or procedures.[29]

In the latter case, research may be conducted only as a "compassionate" procedure not requiring the review of a local ethics board if it is an "emergency" treatment with potential therapeutic value and involving a new or investigational drug or device.

Historically, the impetus for controls on the use of human subjects has been either the documentation of abuse of subjects or questions raised about potentially risky research. In the 1960s and 1970s, studies such as the Milgram "psychology of obedience" project (in which subjects were encouraged to act with increasing severity against other subjects),[30] or the Public Health Service Tuskegee study experiments in which over 300 black prisoners with syphilis were examined and tested but not treated for more than 40 years in order to observe the complications arising during terminal stages of the disease,[31] served to focus public and congressional attention on the need for more formal governmental surveillance of research on human subjects. In these and other cases, critics were able to show that human beings were subjected, usually without their knowledgeable consent, to the risk of some potential harm: death, physical abuse or injury; psychological abuse or injury; damage to interpersonal relations (e.g., loss of trust in others); legal jeopardy (e.g., creating and revealing a record of criminal behavior); career damage; economic harm; or invasions of privacy.[32]

Of all aspects of the human subjects debate perhaps the most sensitive has been the use of subjects with "limited civil freedom," a classification that includes prisoners, residents of institutions for the mentally ill and retarded, and children/minors.[33] As research institutions are often located in large urban areas, subjects are frequently drawn from the disadvantaged in those cities. Hospitalized or incarcerated subjects also provide a convenient, stable population that can be monitored with ease.[34] The large U.S. prison population, in fact, makes it possible for a research project to choose subjects with any necessary characteristic. Proponents of the use of such subjects argue that, moreover, there are also considerable advantages to society: prisoners are provided with a break from monotony, a feeling of altruism, and some monetary reward; research on mental illness and retardation cannot proceed without access to such patients.

Foremost in the discussion of whether minors or institutionalized subjects should be used is the question of coercion; for these subjects' peculiar position renders their "consent" to participation questionable and may also lead to subtle, and often unintended, abuse by experimenters.[35] Opponents argue that because such research may be carried out in prisons or mental hospitals, it does not receive the scrutiny and criticism by colleagues which may be routine or required in normal research settings.

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[29] Robert E. Hodges and William B. Bean, "The Use of Prisoners for Medical Research," *The Journal of the American Medical Association*, vol. 202, Nov. 6, 1967, p. 177.

[30] Stanley Milgram, *Obedience to Authority* (New York: Harper & Row, 1974).

[31] James H. Jones, *Bad Blood: The Tuskegee Syphilis Experiment* (New York: The Free Press, 1981).

[32] Donald P. Warwick, "Types of Harm in Social Research," *Ethical Issues in Social Science Research*, Tom Beauchamp, et al. (eds.) (Baltimore, MD: The Johns Hopkins University Press, 1982), pp. 105-110.

[33] Robert J. Levine, *Ethics and Regulations of Clinical Research* (Baltimore, MD: Urban & Schwarzenberg, 1981).

[34] Ibid.

[35] Alexander M. Capron, "Medical Research in Prisons," *The Hastings Center Report*, June 1973, p. 4.

Concern that special populations might not be adequately covered by existing regulations led in the 1970s to the suggestion of a moratorium on research involving prisoners. In some countries—e.g., England—prisoners may not be used as subjects of experiments. The World Medical Association's *Declaration of Helsinki* (1964, revised in 1975) states that the only appropriate subjects are those "in such a mental, physical, and legal state as to be able to exercise fully [their] power[s] to consent." Dissension over exactly how to treat prisoners has apparently stymied recent Food and Drug Administration efforts to finalize its regulations on such research.

Additional questions may be raised about how human subjects are used in social science research. Quite a bit of controversy arose in the 1960s and 1970s over deception that occurred in such research. Because they used stooges or engaged in covert observation of unsuspecting people, some social scientists appeared to be using "dubious means to achieve questionable ends." The researchers insisted that deception was only used to advance human understanding and thus was beneficial to human welfare, that it helped in the study of "underdog" social groups such as homosexuals, and that deception in research—just as deception in muckraking journalism—could help to expose the unethical conduct of the power elite. Critics argued that any study that involved the violation of moral norms could not advance the human welfare, that "a chain of lies was not morally justified,"[36] and that no gain could offset the magnitude of potential discomfort to the subject.[37]

The tremendous acceleration of medical research—e.g., in immunology, genetics, and biomedical engineering—has created new controversies for those fields. Many medical researchers would like to use new techniques or technologies on patients before they have been fully tested. They believe that if a procedure could help a patient, then they have a responsibility to try it, even if they are not sure it will work. Others believe that the physician's responsibility is to be certain that a technique will result in some benefit. The conflict between these two perspectives raises such questions as: Who is or is not an experimental subject? What are the justifications for delay in using a new technique? Ethicist Thomas Murray has pointed out, in discussion of the "Baby Fae" baboon heart transplant, that even in a desperate therapeutic situation, certain rules should be followed. He suggests that four questions should be asked before an experimental treatment is used: Is the scientific background right? Is the next experimental subject naturally a human being? Is there no superior alternate therapy available? And can the researcher get truly informed consent—or informed consent from a guardian or parent?[38]

Similar questions are being raised for the use of human somatic-cell gene therapy[39] when opponents ask whether such research is playing with the very essence of humanness, or when animal rights groups object to the use of primates as a substitute for human experimental subjects.[40] Those arguing for proceeding with the research cite the potential benefit to existing patients. The "bottom line" for that debate—as with many others—has become, as Alexander Capron has written, "when may a society, actively or by acquiescence, expose some of its members to harm in order to seek benefits for them, for others, or for society as a whole?"[41] In some other contexts, society has already answered Capron's question by putting some people in jeopardy to protect the whole population. We select firemen and members of the military forces, sometimes by conscription, sometimes by lottery, sometimes by offering incentives. We have also used some of these means—incentives and lotteries—to select subjects for experiments.[42]

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[36] Donald P. Warwick, "Social Scientists Ought to Stop Lying," *Psychology Today*, February 1975, pp. 38-40, 105-106.

[37] See Tom L. Beauchamp, et al. (eds.) *Ethical Issues in Social Science Research* (Baltimore, MD: The Johns Hopkins University Press, 1982).

[38] "The MacNeil/Lehrer News Hour: The Baby Fae Case," transcript #2385, *Thirteen*, Nov. 16, 1984, pp. 1-9.

[39] See "Points to Consider in the Design and Submission of Human Somatic-Cell Gene Therapy Protocols," prepared by the Working Group on Human Gene Therapy of the NIH, *Federal Register*, vol. 50, No. 14, Jan. 22, 1985.

[40] Judith A. Johnson, "Human Gene Therapy, Updated 10/30/84," Library of Congress, Congressional Research Service, Science Policy Research Division, Apr. 3, 1984.

[41] Capron, op. cit., p. 4.

In the debates over experimentation on fetuses (either still in the womb or newly aborted or miscarried), the emotionally charged issue of abortion—as a potential "source" of fetuses or fetal tissue—has often been the implicit or explicit justification for controls. (See ch. 4 for discussion of specific regulations on use of fetuses.) Similar debates are now raging in England.[43]

On occasion, objections to research have focused on accusations that a city or special population might be "experimented on." Concern that research might jeopardize the health and safety of the general public was, for example, expressed during the 1970s' recombinant DNA controversy in Cambridge, Massachusetts (see ch. 7).[44] The argument was not that such research was intrinsically "bad" or that it might not result in positive gains for society. The argument was that the safety of the research procedures was untested and the consequences of an accident—even if only remotely possible—were potentially so negative that the community might be unwilling to risk any mistake. In such cases, until the procedures can be proved to be reliable, the public and the legislative bodies have acted to suspend research temporarily—until public study and debate can take place. The Catch-22 in this scenario is often that the procedures cannot be proven to be safe without trying them in some way.

To Protect Animals Used in Experimentation

The first attempts at social regulation to protect the welfare of animals (to obtain legal protection for members of nonhuman species) date to 19th-century England, although social concern—in the form of cultural reverence for some animals, and/or repulsion at cruel treatment of animals—may be found in many countries for hundreds of years.[45]

The controversy over the experimental use of animals is characterized by certainty of moral position on both sides. Thomas H. Moss of Case Western Reserve University observes that:

> . . . those who are convinced that laboratory animals are cruelly or unnecessarily used have often characterized the scientific establishment as insensitive to animal pain, and lacking in basic compassion toward living creatures. Those who are convinced that animal experiments are natural and appropriate tools to serve the advancement of science . . . have often characterized the animal welfare movement as irrational and as blindly myopic in the sense of moral outrage at animal suffering but lack of recognition of human health needs.[46]

In its attempt to abolish totally the use of animals in experiments, the animal liberation movement is saying:

> . . . that animals and humans have similar interests . . . those interests are to be counted equally, with no automatic discount just because one of the beings is not human.

This argument extends to such similarities as avoiding physical pain.[47]

The justifications for the various positions are based on a number of philosophical arguments related to perceptions of the appropriate relationship between humans and animals. Members of the animal *rights* community believe that animals possess a consciousness and certain attributes—e.g., symbolic communication, self-awareness, and anticipation of future events—which imbue animals with rights as exercised by humans. They see the animal rights movement as the progeny of the "humanitarian" movement, as the logical successor to the civil rights movement and the feminist movement. In comparison, the animal *welfare* movement, which includes some animal researchers, believes that as humans, in the words of Arthur Caplan, we hold a certain "moral stewardship" over animals, which requires that we treat them with respect even in the service of humans. The concept of moral stewardship infuses a spectrum of regulatory activity, ranging from outright bans on the use of certain animals (or of any animal in certain types of research) to National Institutes of Health regulations governing the treatment, handling, and use of animals in laboratories. (See ch. 4).*

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[42] Dael Wolfle, Emeritus Professor, Graduate School of Public Affairs, University of Washington, personal communciation, 1985.

[43] See Mary Warnock, *A Question of Life: The Warnock Report on Human Fertilization and Embryology* (New York: Basil Blackwell, Inc., 1985).

[44] Sheldon Krimsky, *Genetic Alchemy: The Social History of the Recombinant DNA Controversy* (Cambridge, MA: The MIT Press, 1982).

[45] Harriet Ritvo, "*Plus Ça Change*: Anti-Vivisection Then and Now," *Science, Technology, & Human Values*, vol. 9, spring 1984, pp. 57-66.

[46] Thomas H. Moss, "The Modern Politics of Laboratory Animal Use," *Science, Technology, & Human Values*, vol. 9, spring 1984, pp. 51-56.

[47] Peter Singer (ed.), *In Defense of Animals* (New York: Basil Blackwell, Inc., 1985), p. 9.

To Protect the Environment

If research involves the use of toxic chemicals or biological materials known or suspected of causing some adverse effect on the environment by altering the natural composition of air, water, or soil, or by destroying or altering the ecological balance, then regulation of the research process may be implemented with the specific intention of protecting the environment.

The dangers in the introduction of new plant or animal species or new genetic forms have been obvious for decades in the destruction caused by, for example, the introduction of such nonnative species as kudzu vine and gypsy moths. Comparison of the effect of a current line of research to the past adverse effects of nondeliberate alterations of the balance between species or environments forms the basis of many attempts to regulate research on environmental grounds.[48] Because it is virtually impossible to design tests to predict the ecological risk from a nonnative species, these concerns have been raised again and again and have now reached the courts via legal action to prevent agricultural research involving deliberate release of genetically engineered bacteria.

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*Concern about this issue has also lead to a National Academy of Sciences study of the numbers of animals used in the United States in research and testing and to an OTA report on *Alternatives to Animal Use in Research, Testing, and Education,* OTA-BA-273, January 1986.

[48] See, for example, Winston J. Brill, "Safety Concerns and Genetic Engineering in Agriculture," *Science,* vol. 227, Jan. 25, 1985, pp. 381-384.

REGULATION OF THE DISSEMINATION OF SCIENTIFIC KNOWLEDGE

Open communication, through such things as publications, symposia, and face-to-face meetings, has always been an essential aspect of scientific endeavor. Unrestricted interaction sets forth a framework within which peer review, criticism, and data sharing can occur; it provides the arena for cross-fertilization of ideas, and helps avoid duplication of effort.[49] As the American Association for the Advancement of Science, Committee on Science in Promotion of Human Welfare, stated in a 1965 report:

> Each separate study of nature yields an approximate result and inevitably contains some errors and omissions. Science gets at the truth by a continuous process of self-examination which remedies omissions and corrects errors. The process requires free disclosure of results, general dissemination of findings, interpretations, conclusions, and widespread verification and criticism of results and conclusions.[50]

Because openness in science also encourages uninhibited dissemination of results outside of the laboratory, the justifications for restraining such communication center primarily around the potential effect of the information, the information's "value" (economic or otherwise), and who is perceived to "own" the information (e.g., the scientist or the organization that supported the scientist's work).

Regulation of scientific communication is far from simply a process of stamping a label on a document, however; it involves restraints or controls on, for example: 1) who may know certain scientific data or information, 2) the dissemination of printed documents, 3) who has access to an electronic communication system, 4) descriptions of processes or computer programs, and 5) even who may share or receive certain cell lines or biological strains.[51] Physicist Lee Grodzins has pointed out that the appropriate point of classification often may not be a specific formula or instruction but the knowledge that a result can be accomplished, for "once it is disclosed that something can be done, then someone will be able to duplicate it."[52] Joan Bromberg, a historian of science, adds that "keeping secret that a research program *exists* is one way to hold the edge in a field," because such "revelations also give hints at the correct direction for research."[53]

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[49] NATO Science Committee, "Open Communication in Science," *NATO Science & Society,* 1983.

[50] Harold C. Relyea, "Shrouding the Endless Frontier—Scientific Communication and National Security: The Search for Balance," *Striking a Balance: National Security and Scientific Freedom,* Harold C. Relyea (ed.) (Washington, DC: American Association for the Advancement of Science, 1985), p. 76.

Because of the differing values of the groups involved in the communication of science, the information developed during research frequently becomes the object of dispute or tension between those who sponsor and those who conduct research. In general, this tension derives from conflicting desires to disseminate and to restrict access to information. As each actor defines differently the areas of restriction, then the tension grows.

This tension is particularly apparent in contemporary restraints on communications relating to national security and commercial property rights in such things as biological materials. In these cases, a lack of consensus on boundary definitions has resulted in increasingly large "gray areas" of information perceived as possible candidates for restriction in the future. The more that military systems depend on advanced technology—including such things as large-scale integrated circuitry, space technology, and microbiology[54]—the more that basic research appears to have the potential for military importance. For technology related to international industrial competition, similar uncertainty about what may prove to be important in the future has stimulated restrictions on the sharing of information with citizens of other countries and on the freedom of industrial scientists or industry-supported university professors to converse openly with their colleagues about their work.

Four main rationales may underpin actions to restrict communication:

- to uphold scientific standards;
- to protect a professional or economic interest;
- to protect the health, privacy, or safety of individuals; and
- to protect national military and economic security.

To Uphold Scientific Standards

Within science, both traditions and good laboratory practice govern the flow of dissemination of research results—who can communicate, who will receive communications, and when and where communication takes place. A junior member of a research team may be restricted from discussing his or her own original work until the team's publication is ready, or scientists in one laboratory group may refrain from discussing their work with colleagues elsewhere in the organization or with journalists until a writeup is submitted to a scientific journal. The ultimate justification for most such controls—whether reinforced by laboratory "rules" or by the pressure of tradition—is to uphold scientific standards, to assure that only verifiable and replicable science is presented as legitimate science.

The peer review system in scientific journals, for example, seeks to filter out reports of scientific work that do not meet the highest standards of research in the field. Readers must be able to accept publication confidently as a seal of legitimacy and accuracy, thereby allowing them to trust the author's conclusions without replicating the experiment or redoing the research. In theory, the norms of good scientific practice justify acceptance or rejection of communications; in practice, the current agenda and occasionally the biases of the research field may determine which topics are favored as well as which determine the mode of presentation.

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[51] Patrick D. Kelley and Ernest G. Jaworski, "Agreements Covering Exchanges of Biological Materials," American Association for the Advancement of Science, annual meeting, New York, May 1984.

[52] "Openness and Secrecy in Scientific and Technical Communication," Seminar, Dec. 11, 1984, Massachusetts Institute of Technology, Cambridge, MA.

[53] Ibid.

[54] NATO Science Committee, op. cit.

The goal of preserving the quality and integrity of science, and the goal of protecting the public are both used to justify an unusual but effective restriction on the timing and, in a few cases, the actual publication of articles in medicine. In 1969, Franz J. Ingelfinger, editor of *The New England Journal of Medicine,* began to worry that premature disclosure of unevaluated and unauthenticated medical research results before they were published in a peer-reviewed medical journal (and hence presumed to be evaluated and authenticated) could be dangerous to the public. He argued that such reports might contribute to false expectations of unevaluated drugs or treatments or, on occasion, might advocate treatments later found to be useless or potentially harmful.[55] Ingelfinger therefore instituted an editorial policy that denied publication to an article if its conclusions or major data had appeared in a medical news publication or similar unrefereed format. This rule has been continued and reinforced by the *Journal's* subsequent editor,[56] and similar practices are followed by editors at other journals.

To Protect a Professional or Economic Interest

Scientists have always exercised a form of self-regulation in publication in order to achieve personal or professional rewards. Timing and placement of publication, for example, can significantly affect a scientist's career success.

Protecting an economic advantage has also long been accepted as a legitimate motive for communications restraint in commercial circles; businesses control publication to protect their economic rights in the material, to make a profit, or to avoid a loss. Examples of such motivations for restrictions may be the protection of patent rights, the maintenance of competitive advantage, or the protection of rights in biological materials.[57] Industry, in fact, has cited the ability to protect intellectual property as a major determinant of success:

> There is a direct correlation between the security of patent rights and industry's willingness to commit large sums to the inherently risky efforts needed to find and develop new technologies.[58]

In industrial research, the sponsor wants to protect the proprietary nature of the research and may not want competitors to have access to the information resulting from the sponsored research. This justification for secrecy now extends widely as more and more universities enter into research agreements with industrial sponsors. The institutions' naturally opposing views about the value of information are often a subject of negotiation in university-industry relations, where the traditional openness of the university could act against the commercial interests. Most frequently, the resolution is a contract provision that allows a prespecified delay of publication in order to permit the sponsor to file a patent application. Some university research projects will submit to a delay to allow an industrial sponsor to review a document for proprietary data.

A desire to secure or protect certain legal rights of the generator or sponsor of the research may also motivate restrictions. With respect to new products or processes developed during research, three outcomes are possible: it may be kept secret; it may enter the public domain; or it may be granted a patent. The patent laws grant an exclusive right, for a fixed period of time, to commercial exploitation of an innovative product or process to the person who discloses the invention to the U.S. Patent Office. Data or analyses collected during research may also receive protection via the copyright laws, which prevent plagiarism. The first U.S. regulation concerning the use of research results was, in fact, stated in the patent and copyright clause of the Constitution.[59]

Premature disclosure of patentable information could endanger the legal rights of the inventor and therefore restriction is chosen. In other cases, disclosure might be used to establish some such right.

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[55] Barbara J. Culliton, "Dual Publication: 'Ingelfinger Rule' Debated by Scientists and Press," *Science,* vol. 176, June 30, 1972, pp. 1403-1405.

[56] Arnold S. Relman, "The Ingelfinger Rule," *The New England Journal of Medicine,* vol. 305, 1981, pp. 824-826.

[57] Kelley and Jaworski, op. cit.

[58] Alexander MacLachlan, testimony before the U.S. Congress, Science Policy Task Force, House Committee on Science and Technology, Apr. 25, 1985.

[59] Harold Relyea, Congressional Research Service, personal communication, 1985.

An organization may take action to impede dissemination (or to hasten dissemination) in order to preserve a corporate image or administrative power. Similar action might be taken to support the mission of a government agency. In a few reported cases, businesses have acted to impede the dissemination of scientific data in order to protect the company's legal position or to avoid adverse publicity. When studies of the toxic effects of vinyl chloride on rats revealed cancer, one Italian researcher, for example, found that his industrial sponsor refused to let the evidence be released. It was some time after that suppression occurred that cancers were found in workers in the United States who had been exposed to vinyl chloride.[60]

To Protect the Health, Privacy, or Safety of Individuals

Federal regulations as well as informal controls on the publication of data from human subjects research often seek to control dissemination in order to *protect the privacy or safety of individuals described in the reports,* or to protect subjects who participate in research on controversial topics or illegal activity.[61]

Some research information may have the potential of harm to the public welfare either because of what is said or when it is said. In those cases, dissemination is regulated (delayed or prohibited) *to protect the public health and safety.* Announcements pertaining to some real or potential public health problems could cause panic, and so restraint is used in the dissemination or publicity prior to publication—a justification that has been used for restricting communication of data on possible modes of transmittal of acquired immunodeficiency syndrome (AIDS). Dissemination of a result may also be delayed or controlled to prevent a potential adverse economic, social, or political reaction. This justification is used to avoid the panic or devaluation of property that might follow publication of an earthquake prediction for a specific area. The "Paigen" report, which analyzed the alleged health effects of the chemicals dumped at Love Canal, was later criticized by a panel of scientists for improper epidemiologic methods that "fueled rather than resolved public anxiety."[62] One of the most important questions raised in such situations is how, in the face of great scientific uncertainty, adverse economic effects should be weighed against possible health risks to individuals or the general public.

Opponents of such restrictions argue that they inhibit free discussion in a democracy. The American public has a right to be told the technical information, even if the public policy decisions are ultimately based on normative rather than technical grounds. In the laser isotope separation case discussed earlier in this chapter, the argument was made that severe classification of such research might not, in the long run, prevent dissemination of the scientific "trick" or secret of the laser isotope separation process to other countries, but that it *could* discourage public discussion in the United States on whether the work should continue. The "lid of secrecy" would "effectively preclude public scrutiny," one observer wrote.[63]

To Protect National Military and Economic Security

Protection of national security has been used for centuries as a justification for government regulation of technical information.[64] During World War II, American scientists and engineers accepted two kinds of censorship or control of communications—voluntary (justified in the spirit of patriotism) and mandatory. Scientific journal editors practiced extensive voluntary censorship during the war—they believed that some type of censorship was necessary to prevent the leakage of vital information to U.S. enemies.[65] Scientific publications of all types were also subject to mandatory review by the Office of Censorship. And scientists engaged in weapons research were, of course, subject to the military's restraints and controls on all their activities, including conversations as well as written communications. In peacetime, however, the "conflicting imperatives of national security and open scientific communication" have occasionally led to controversy and legal action and are continually the subject of vigorous debate.[66] The tension between these two objectives arises primarily in a clash between the justifications for restraint and openness. The government wants to control all information that could be of possible value to potential enemy states; the scientists stress that such measures could damage scientific progress and creativity and abridge traditional scientific freedom.[67]

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[60] John T. Edsall, "Scientific Freedom and Responsibility: Report of the AAAS Committee on Scientific Freedom and Responsibility," *Science,* vol. 188, May 16, 1975, pp. 687-693, and vol. 189, July 18, 1975, pp. 174-175.

[61] Barry Barnes, *Who Should Know What: Social Science, Privacy and Ethics* (Cambridge, England: Cambridge University Press, 1979).

[62] Lewis Regenstein, *America the Poisoned* (Washington, DC: Acropolis Books Ltd., 1982), p. 140.

[63] Casper, "Laser Enrichment," op. cit., p. 38.

[64] Relyea, "Shrouding the Endless Frontier," op. cit., p. 80.

[65] Michael M. Sokal, "Restrictions on Scientific Publication," *Science,* vol. 215, Mar. 5, 1982, p. 1182; and Michael M. Sokal and Janice F. Goldblum, "From the Archives," *Science, Technology, & Human Values,* vol. 10, spring 1985, pp. 24-27.

The motives for restrictions justified by national security can be both economic and military. Often, the restriction is indicative of whether the research has demonstrated application.[*] Although "national security" is vaguely defined in the law and the uses of the term range from "defense of the United States" and "public peace and safety" to "financial policies of the United States," there is agreement among policy analysts that that policy concept does provide to the President a broad grant of administrative discretion to justify all sorts of policies.

Recently, the justifications for communications restraints based on national security considerations have tended to relate to quite specific perceptions about the importance of science in an international context. First, those who believe that the United States' lead over the Soviet Union in some important areas of military technologies is diminishing attribute that situation to Soviet absorption of U.S. technologies. Second, the military systems themselves have become more dependent on sophisticated new technologies and on the science that feeds them. Third, proponents of restrictions believe that a steadily increasing share of these technologies is dual-use in nature, that is, that they can have both military and nonmilitary applications.[68] And fourth, such national policies as East-West détente and scientific exchanges with the Chinese are perceived to have increased the opportunities for leakage of technical information of all types. Such rationales were clearly stated in the draft "National Policy on the Transfer of Scientific and Technical Information," issued by the executive branch on June 15, 1984:

> The acquisition of advanced technology from the United States by Eastern Bloc nations for the purpose of enhancing their military capabilities poses a significant threat to our national security. Intelligence studies indicate that a small but significant target of the Eastern Bloc intelligence gathering effort is science and engineering research performed at universities and federal laboratories. At the same time, our leadership position in science and technology is an essential element in our economic and physical security. The strength of American science requires a research environment conducive to creativity, an environment in which the free exchange of ideas is a vital component.[69]

The government has recently justified the application of export control regulations to basic research as necessary to protect: 1) tangible goods, including technical data, that relate to national security; and 2) the domestic economy. The application limits "information of any kind that can be used or adapted for use, in the design, production, manufacture, utilization, or reconstruction of articles or materials."[70]

The ensuing controversy over the wide-scale application of these controls has led to a reaffirmation by the Department of Defense/University Forum that: "No restriction may be placed upon the conduct or reporting of fundamental research that has not received national security classification." However, how the various participants in such restrictions define what is or is not funamental research can determine the extent of re- riction. This window of uncertainty prompted e Department of Defense (DOD) to state its def- ition of "fundamental research":

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[66] Richard D. DeLauer, "Scientific Communication and National Security," *Science*, vol. 226, Oct. 5, 1984, p. 9.

[67] NATO Science Committee, op. cit.

[*] ". . . know-how is a precious commodity leading to the commercial or military products that determine the fortunes of nations in peace and in war. Yet sometimes it is hard to tell where scientific knowledge leaves off and engineering know-how begins." DeLauer, op. cit.

[68] Panel on Scientific Communication and National Security Committee on Science, Engineering, and Public Policy, *Scientific Communication and National Security* (Washington, DC: National Academy Press, 1982), p. 11.

[69] U.S. Congress, "Scientific Communication and National Security," hearings before the House Committee on Science and Technology, May 25, 1984.

[70] 15 CFR 379.1.a.

> For DOD purposes the decision whether a particular research activity is or is not fundamental will be determined primarily by considering the following easily identified characteristics: 1) performer (for example, university, industry, in-house) 2) budget category (for example, 6.1, 6.2) 3) sponsoring DOD entity 4) special contract provisions. . . . Unclassified contract research supported by 6.1 funding shall be considered 'fundamental.' Similarly, unclassified research performed on campus at a university and supported by 6.2 funding shall with rare exceptions be considered 'fundamental.'[71]

In the disputes over restrictions on scientific mmunication, DOD sees itself as "caught in a lemma." In the words of the Defense Science oard:

> If it vigorously attempts to regulate the flow of scientific information in the scientific community, it could jeopardize the strength and vitality of the very community it is seeking to revitalize for the sake of national defense. On the other hand, if DOD abandons any attempt at regulation in the university context, it could seriously compromise and, in certain cases, totally undercut other efforts to control the out-flow of militarily critical technology. The middle ground is a difficult one to establish.[72]

The Corson panel of the National Academy of Sciences, fearful that the government policy could begin to endorse a form of "blanket justification" for restricting some fields of basic research, attempted to clarify the limits of acceptable restraints. The Corson panel's report[73] stated that communication restrictions should not be applied to any area of university research, be it basic or applied, unless they involve a technology meeting all the following criteria:

> The technology is developing rapidly, and the time from basic science to application is short; The technology has identifiable direct military applications; or it is dual-use and involves process or production-related techniques; Transfer of the technology would give the U.S.S.R a significant near-term military benefit; and the U.S. is the only source of information about the technology, or other friendly nations that could also be the source have control systems as secure as ours.[74]

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[71] Leo Young, "Commentary: The Control of Government-Spon- red Technical Information," *Science, Technology, & Human Val- s*, vol. 10, spring 1985, pp. 82-86.

[72] Report of the Defense Science Board Task Force in University Responsiveness to National Security Requirements, January 1982.

[73] Panel on Scientific Communication, op. cit.

[74] Ibid.

UMMARY

In 1979, Miller, Prewitt, and Pearson conducted public opinion poll for the National Science undation in which they asked respondents out specific types of scientific studies and hether scientists should be "allowed" to conduct ose studies. Because the structure of the poll estions implied regulation, the response can be terpreted as one measure of the public's will- gness to restrain certain types of scientific in- iiry.[75] The results indicate that a majority of the spondents would have liked to prohibit research aling with the creation of new life forms and ith the gender of children. Opposition to genetic engineering declined some when the question specified plants and animals rather than humans, but there was still substantial disapproval of scientific research in this area. In contrast, only one-quarter of the population expressed opposition to studies that would involve weather modification or the extension of the average human life span.

Such data tend to indicate that Americans, in deciding whether research should be restricted or prohibited, may make such decisions based on whether they believe that the restriction would respond to moral or social objections. The results may also indicate that the public is more likely to approve regulation for reasons relating to the immediate protection of human health or safety or to preservation of the moral order than for reasons relating to potential long-term damage of the environment or depletion of economic resources.

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[75] Jon D. Miller, et al., *The Attitudes of the U.S. Public Toward ence and Technology* (Washington, DC: National Science Foun- ion, 1980); also Jon D. Miller, *The American People and Science licy* (New York: Pergamon Press, 1983).

Although most Americans believe that the government has some control over the work of scientists, the public does not appear to be willing to endorse more direct public control. A 1983 Annenberg study asked whether the government presently has any control over "what scientists do" and 77 percent of the respondents indicated that they thought that the government did have that kind of control.[76] When asked if the government "should" have control over what scientists do, 67 percent of the public agreed that this kind of control was appropriate. In a 1979 study, respondents were asked whether "most citizens are well enough informed" to help set goals for scientific research or to decide which new technologies should be developed.[77] Approximately 85 percent of the public indicated that they did not feel that most citizens had the knowledge needed either to set research goals or to select technologies.[78] Contradictory evidence of such willingness to participate was found, however, in a pilot study conducted in 1979 by the Public Agenda Foundation, which concluded that public participation in decisionmaking can extend to priority-setting based on limiting or restraining certain areas of research.[79]

Available public opinion data suggest that the public is not unwilling, based on a number of rationales, to restrict the scope of scientific inquiry, especially in the area of human health and safety such as genetic engineering. The data also suggest that a larger portion of the public would be comfortable with the genetic modification of plants and animals, but that there is substantial concern about work involving changes in the human genetic structure. Other evidence, such as increased demonstrations, publicity, and legislative initiatives, indicates that, in the eyes of the general public, some regulation of experimentation on animals is supported.

It is possible that because the public appears to place such high value on science's contribution to human health and to quality of life, and because usefulness and application play such a significant role in the public's evaluation of scientific priorities, a willingness to regulate may indicate that, in such instances, the perceived risk is believed to outweigh perceived benefit, even though there may be inadequate evidence to support either position.

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[76] Miller, *The American People and Science Policy*, op. cit.

[77] Miller, et al., op. cit.

[78] Ibid.

[79] Public Agenda Foundation, *Science Policy Priorities and the Public*, a report to the National Science Foundation on a Pilot Project to Assess Public Attitudes About Priorities and Indicators of Quality for Scientific Research, New York, 1983.

Chapter 4

The Mechanisms for Direct Control of Research

Photo credit: National Institutes of Health

Chapter 4

The Mechanisms for Direct Control of Research

At the laboratory bench level, each researcher controls his or her own activities, deciding which questions to answer and how to go about answering them. Controls are also part of the normal procedures of a research field or discipline—for example, the peer review system that governs the contents of disciplinary journals. Other, more formal control takes place at the laboratory or institutional level, through set policies or such mechanisms as review committees. And finally, legal and administrative regulation of research occurs at all levels of government, most likely in response to public opinion or public protest. This chapter looks at the administrative mechanisms for control or influence at all stages of the research process.

In an idealized model of scientific freedom, a scientist sets his or her own research agenda, performs the research without fear of repercussion or criticism, and describes the work to anyone and everyone. Sissela Bok characterizes such freedom as "freedom of limitless thought and unfettered speech."[1] For scientists in some fields, that freedom has traditionally been perceived to encompass autonomy of action as well as responsibility for how the work is conducted. Biologist David Baltimore observes that contemporary research in molecular biology, for example:

> . . . has grown up in an era of almost complete permissiveness. Its practitioners have been allowed to decide their own priorities and have met with virtually no restraints on the types of work they can do.[2]

In many research facilities and in many laboratories, open communication has been routine. Zoologist Alexander Faberge describes the "open traditions" in one field:[3]

> Not only is it normal to discuss one's ongoing research, but also to give away one's research material in the form of genetic stocks, with the verbal understanding that the giver should be given time to publish first. Such genetic stocks, or cultures of organisms, sometimes take years of work to prepare, and are placed in culture collections, freely available.

"It would be an unheard of matter," Faberge continues "to keep genetic stocks private . . ." These and similar aspects of the sharing of research data are discussed in a 1985 report from the National Academy of Sciences (NAS) which notes that, in general, access helps in reanalysis and verification.[4] In fast-moving areas, the sharing of research data may jeopardize a researcher's patent rights or the commercial return on a discovery, so there are significant forces against openness. Nevertheless, the NAS committee concluded that without data sharing, scientific understanding and progress would be impeded.

Even in early modern science, however, communication of ideas was not totally open. Inventors delayed or repressed publication out of fear of ecclesiastical or political displeasure. Because the community of science rewards priority, researchers have also delayed sharing data until credit is assured, usually through publication. Historian David Hull attributes such secretiveness to science's "intrinsic competitive nature."[5] Technological skills and knowledge regarded as applied have not always been tightly controlled by their possessors; skills were assumed to be the property of those who exercised and developed them.[6] Although *unqualified* sharing (especially before publication) has never been the norm, until several decades ago, scientists exercised relatively few restraints on their communications to others.

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[1] Sissela Bok, "Freedom and Risk," *Limits of Scientific Inquiry*, Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), p. 116.

[2] David Baltimore, "A Biologist's Perspective," *Limits of Scientific Inquiry*, Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), p. 37.

[3] Alexander C. Faberge, "Thoughts on the Origins of Secrecy and Openness in Science," American Association for the Advancement of Science, annual meeting, New York City, May 1984.

[4] National Academy of Sciences, Committee on National Statistics, *Sharing Research Data* (Washington, DC: National Academy Press, 1985).

[5] David Hull, "Openness and Secrecy in Science: Their Origins and Limitations," *Science, Technology, & Human Values*, vol. 10, spring 1985, pp. 8-9.

Contemporary attitudes to openness in university science are also influenced by the concept of academic freedom in general. In the United States, "academic freedom" has stood for personal freedom of the academic, rather than the collective freedom of the Nation. Because of this emphasis on the individual, some academics have regarded regulation more as a limit to which they are *obliged* to submit. Limits have been, therefore, equated with "responsibilities."[7] But, Walter Metzger points out, "academic freedom and scientific freedom are different species of freedom. . . ."[8] The former is an ideology of a profession, across the disciplines, with common duties; the latter is the ideology of various professions in a discipline (e.g., science). And the latter need not be connected to a university.

Historian Carroll Pursell takes a more pragmatic view. Science, he observes, is always "regulated" in the sense that it is given shape, direction, and impetus by something. There is, he writes, "a tendency to take it simply as the working of some invisible hand until the public (in the form of government, mobs, or whatever) takes a more visible hand. This is, of course, nonsense."[9] Communities have, for example, never tolerated (for very long) any researcher who tackles topics outside the boundaries of accepted moral behavior or social beliefs or who knowingly puts the community at risk through hazardous, dangerous procedures (e.g., experimenting with explosives in Times Square). Such "moral regulations"—enforced through social condemnation or disapproval—have been the predominant controls on research for centuries, other than those which arose in connection with military research. Neither Federal nor local governments in the United States had formal laws, rules, or policies by which the subjects or procedures could be controlled.

This environment changed for American scientists in the 1940s. When the United States entered World War II, the scientific community joined in the war effort and, just like millions of other people, scientists relinquished to the Government their personal autonomy over how they did their work. They accepted government control over agenda, over process, and—in the case of information considered to be of military importance—over dissemination even to their colleagues. When almost everyone in science was working behind the secrecy fence, the communications restrictions did not seem so onerous. There was a comraderie and free exchange that participants recall as frequently greater than in the structure of university departments. Within the Manhattan Project, for example, Robert Oppenheimer successfully convinced General Leslie Groves not to implement irrevocable application of "compartmentalization." Groves wanted to keep scientists from sharing information with their colleagues in other parts of the project; Oppenheimer argued that some decompartmentalization was necessary for progress at both the laboratory and the individual level. The perspective argued by Oppenheimer was that the scientists were the best judge of how to get to their goal. He also believed that the creative scientist required intellectual "elbow room" for the cross-fertilization that could be vital in a new field. Each individual had to feel free to pursue research whatever way he or she wished.

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[6] Ernan McMullin, "Openness and Secrecy in Science: Some Notes on Early History," *Science, Technology, & Human Values*, vol. 10, spring 1985, pp. 14-23.

[7] Walter P. Metzger, "Academic Freedom and Scientific Freedom," *Limits of Scientific Inquiry*, Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), p. 102.

[8] Ibid., p. 107.

[9] Carroll Pursell, Department of History, University of California, Santa Barbara, personal communication, 1985.

MECHANISMS FOR INDIVIDUAL OR RESEARCH GROUP CONTROL

At the level of individual choice, then, researchers in a democratic system decide what line of research to pursue, how to test their hypotheses, which data to gather and how to gather it, and when and to whom to tell about their results. The scientists simply seize on personal freedoms available to all citizens.

The amateur astronomer provides an excellent example of how little externally imposed controls can affect a researcher who is working outside conventional institutional settings for research, academic or otherwise. There are approximately 10,000 amateur astronomers in the United States, many of them engaged in the search for new astronomical bodies, or in recording astronomical phenomena. Almost all work at their own expense, in return for the reward of discovery, the joy of creative activity. Such an individual can decide what to do, can build his or her own equipment according to any schedule, and can elect to tell everyone or no one* about the results. To achieve recognition and acceptance by the community of professional astronomers, however, a researcher must adhere to the standards and norms that govern conduct in the field and must subject that work to review by colleagues, usually through the journal peer review system.

Agenda Controls

In research groups, internal factors may not only direct but also constrain research. At any given point in the development of a scientific speciality, for example, there exists some finite set of research topics that are considered by the members of the speciality to be legitimate, interesting, and feasible.[10] If peers do not consider an area to contain "interesting" questions and hence to be intellectually stimulating or professionally rewarding, then researchers may suspend research out of concern for their professional reputations. Influence on the researchers to control or restrain their own work may also come from the social environment, as when the public raises questions about the morality of a project. Other research topics may receive little attention and no funding because peers consider them to be outside the boundaries of "legitimate" science; research on parapsychology often falls into this category. Researchers working on new chemicals for introduction into commerce or on new pesticide formulations may tend to shape their investigations so that the chemical will withstand scrutiny and secure approval under such Federal environmental regulations as the Toxic Substances Control Act or the Federal pesticide laws.

The cost of instrumentation and the internal allocation of resources can be devices for dramatically controlling the research agenda. The major experimental facilities for high energy particle physics research, for example, are few in number and because the demand for time on the accelerators far exceeds the time available, laboratories

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*A participant in a 1984 seminar series sponsored by the American Association for the Advancement of Science pointed out that when an idea is in a researcher's head and not written up, then of course there is no real dissemination subject to regulation. Once it becomes more than an idea, then the law can regulate it as speech. If you tell enough people (as legally defined), then that is considered to be publication and the government can step in (in the case, for example, of information relevant to national security interests). This issue arises in conjunction with interpretation of the Export Administration Act of 1985, which permits restrictions on "information and knowhow (whether in tangible form . . . or in intangible form). . . ." The question for future cases will be can this be construed to mean knowledge in a scientist's head.

[10] Daryl E. Chubin and Terence Connolly, "Research Trails and Science Policies: Local and Extra-Local Negotiation of Scientific Work," *Scientific Establishments and Hierarchies: Sociology of the Sciences*, vol. 6, Norbert Elias, et al. (eds.) (Hingham, MA: Reidel Holland, 1982), p. 293.

Box A.—NIH Study Sections as a Mechanism for Control of Agenda

The peer review system, whereby scientists advise the Federal Government on how to allocate research funds, is representative of a two-pronged mechanism for control of the research agenda: decisions on funding particular proposals both set the current agenda for research and affect the direction of a field or discipline. The multi-level process used by NIH provides a good example of such controls.

A research proposal submitted to NIH is first scanned by an officer in the Division of Research Grants, who refers the proposal to the most relevant of 65 chartered study sections and to the most appropriate Institute of NIH. Each study section is composed of approximately 18 scientists and a full-time, nonvoting executive secretary who is an NIH scientist. The executive secretary nominates members of the study section for selection by the NIH Director. Study section members serve a 4-year term and meet 3 times a year to review over 100 proposals per session.

The study sections assign to each proposal a priority score based on scientific merit. Reviewers are not aware of the total budgetary request on the proposal. The relevant Institute then receives the ranked proposals and passes the funding decision on to its advisory council, which is composed of both scientists and public figures. Because Institutes with larger budgets are able to fund more projects, some critics charge that high quality research can go unfunded in areas where social and political decisions have resulted in a lower priority for certain diseases and that lesser quality research may be funded in more "glamorous" disease categories. The study sections also conduct workshops to report on the status of the field, thereby providing long-term planning information to the Institute directors and sending signals to the scientific community about areas of potential interest to the granting agency.

adopt specific criteria for selecting experiments and assigning priorities to them. The International Committee for Future Accelerators of the International Union of Pure and Applied Physics recommends four criteria be used for selecting experiments and determining their priority: 1) scientific merit, 2) technical feasibility, 3) capability of the experimental group, and 4) availability of the resources required.

At the individual level, research may be restricted not only by mechanisms driven by political, economic, or professional concerns but also by personal values. Especially when alternatives are limited, individuals "feel forced to choose among projects they would normally not consider, the moral questions . . . become more immediate and controversial."[11] The decision not to participate in military-supported or weapons-related research, therefore, may be also a decision to alter one's lifetime research agenda. This decision is a personal one, an individual rather than a collective control.[12]

In each of these instances, the regulatory force may actually be outside the research group, but the group or the individual chooses to suspend a line of research in response to either moral or economic pressure.

Controls on Procedures

Within each scientific field or research speciality, the social influence of tradition and "standard practice" also govern aspects of the research process. Even though these practices are voluntary, they carry the authority of social norms. On occasion, they may later form the basis for institutional or governmental regulation.

Many controls are linked to the formal principles and rules that govern admission to a profession. Since antiquity, the medical profession, for example, "has formalized principles and rules of conduct for its members in prayers, oaths, and codes."[13] Universal codes adopted by more than one scientific field may relate basic ethical and moral principles to research practice. The Nuremberg Code of 1947, for example, serves as the model for many international and national codes pertaining to clinical research in general and to such topics as organ transplantation.[14] Another important code has been the World Medical Association's Declaration of Helsinki (1964, revised 1975).

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[11] Rosemary Chalk, "Drawing the Line: Science and Military Research," unpublished manuscript, May 1983, p. 24.

[12] Ibid., p. 22.

[13] Judith P. Swazey, "Protecting the 'Animal of Necessity': Limits to Inquiry in Clinical Investigation," Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), p. 136.

[14] Ibid., p. 132.

In some research areas, laboratory groups have not refrained from imposing voluntary clinical moratoria—prohibiting researchers from, for example, using on patients a procedure still considered to be experimental. Such a moratorium can last weeks, even years.[15] It is linked to perceptions of the risks associated with premature use of a procedure and to the incomplete nature of the research process, however, not to the topic.

The most dramatic instance of a voluntary moratorium on basic research was, of course, that imposed by molecular biologists in the 1970s. Recombinant DNA regulation arose first in the form of a moratorium called by researchers in the field. What began in private discussions was dramatically brought to public attention when, as described in chapter 2, biologists proposed a voluntary suspension of certain types of genetic research. This extraordinary step was followed by the 1975 Asilomar meeting, when researchers from the United States and elsewhere, discussed the appropriateness of continuing the moratorium. After that meeting, action moved to the Federal Government level—to legislation and the formal development of National Institutes of Health (NIH) guidelines for the research.

Communication Controls

Through the centuries, individuals have also exercised self-restraint in dissemination of research results, either by withholding the information altogether or by delaying dissemination for a short period of time. British mathematician John Napier, who had experimented with a new form of artillery around 1600, "took great pains to conceal the workings of his invention."[16] In 1947, Massachusetts Institute of Technology professor Norbert Weiner refused to supply a paper of his to an industry scientist engaged in military research.[17] In the 1980s, many biologists assert that researchers in certain areas are refraining from sharing information and substances with colleagues.[18]

The science community as a whole may support an investigator's desire to avoid premature disclosure, especially when data are incomplete or not yet published in a refereed journal. Such delay may also be linked to the researcher's desire to maintain professional security through temporary but exclusive control of knowledge. A dramatic example of group self-censorship occurred before World War II when a group of physicists tried to limit the publication of scientific research relating to nuclear fission. By the middle of 1940, most physics journals had agreed informally "to delay the publication of any article that might help a knowledgeable scientist build an atomic bomb."[19]

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[15] Judith P. Swazey and Renee C. Fox, "The Clinical Moratorium: A Case of Mitral Valve Surgery," *Experimentation With Human Subjects*, Paul A. Freund (ed.) (New York: George Braziller, 1969).

[16] Cited in Chalk, op. cit., p. 9.

[17] Norbert Weiner, *The Atlantic Monthly*, letter to the editor, January 1947; reprinted in *Science, Technology, & Human Values*, vol. 8, No. 3, summer 1983.

[18] Biologists interviewed by Sandra Panem "uniformly agreed that there was more . . . free information exchange in the 1960s than currently." Sandra Panem, "The Interferon Dilemma: Secrecy v. Open Exchange," *The Brookings Review*, winter 1982, p. 20.

[19] Michael M. Sokal and Janice F. Goldblum, "From the Archives," *Science, Technology, & Human Values*, vol. 10, spring 1985, p. 24.

REGULATIONS IMPOSED BY INSTITUTIONS

The attitudes and policies of research organizations can regulate the agenda, procedures, and communication of a project, through both informal guidelines enforced by social pressure and formal rules enforced by threat of dismissal or penalty. Although the extent and stringency of rules may vary, most organizations have specific experimental protocols and safety procedures and have policies on what subjects are not acceptable. A research group may decide deliberately to take up or drop a specific line of research for political or moral as well as scientific considerations. Those decisions—whether to pursue certain topics, or how to disseminate results—can reflect such factors as: 1) fear of social criticism or protest, 2) accommodation to the pressures of the surrounding social or political climate, or 3) a desire to protect property rights (e.g., when a team delays publication until assured of patent protection or keeps a project secret in order to assure first publication).[20]

As a result of discussions from the Vietnam era, some U.S. research laboratories or universities decided not to allow classified research to be performed on their campuses.[21] Ohio State University, which accepted over $5 million in defense contracts research in 1982, now bans any campus research on offensive weapons.[22] Other universities impose procedural restrictions—e.g., whether classified work may be accepted with any entailing restrictions on publication[23]—or have placed such work off-campus and attempted to insulate it from the research environment of undergraduate or graduate students.

To enforce such administrative policies on acceptable research topics or procedures, organizations employ a variety of mechanisms, ranging from informal guidelines and review committees, to formal administrative rules. In most cases, these controls are enforced through social pressure or reprimand. Many universities have adopted guidelines for the acceptance of externally sponsored research which govern, for example, the terms of university-industry cooperative projects, the use of human subjects in experiments, or the handling of dangerous biological materials.[24] Such policy documents may govern with a velvet glove, however. As the Harvard University guidelines note, "The pursuit of truth in the academic community is impossible without a measure of mutual trust between its members, and no set of detailed principles and criteria can be a substitute for this trust."[25] The Harvard report further points out that:

> . . . the principal means by which the faculty exercises control over the quality of the scholarly activities of its members is through its role in recommending the selection of its own members and through the professional standards that it and the University apply in the selection process.[26]

To administer such rules on a routine basis, universities and private laboratories set up institutional committees to review safety procedures, to decide which topics to pursue, or to review the quality or process of publication. Committees are dominated by members of the institution and are appointed and funded by the institution. Many exist as a direct result of Federal regulations tied to grant or contract funds. Institutional Animal Care and Use Committees, Institutional Review Boards, and the Institutional Biosafety Committees, for example, are all required of institutions receiving funds from the Public Health Service, NIH, or other compliant agencies. Institutional review boards, which are (administratively and financially) local committees of the institution, nevertheless must include both scientists and nonscientist members from the local community, all of whom "examine and pass judgment on the risks and benefits of a proposed study and on the adequacy of the consent proceeding as described in the research protocol."[27]

Some institutional committees govern the administration of a specific research program. For example, in 1977, the Monsanto Co. and Harvard University set up a special independent advisory committee to oversee aspects of their $23 million research agreement. The five-person committee, established out of concern for the public interest, assures that "both sides honor their contractual promises to protect academic freedom—namely, the right to publish—and to develop any products that may emerge in a manner consistent with the public good."[28] The Health Effects Institute, a private research firm, insulates scientists from pressure by using two independent committees, one that creates the research agenda, another that reviews finished work.[29] In the national laboratories, visiting committees, composed of scientists from other institutions, are used to evaluate the quality of work in the lab.

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[20] As described in, for example, James D. Watson, *The Double Helix* (New York: Atheneum, 1968).

[21] Robert C. Cowan, "Degrees of Freedom," *Technology Review*, August/September 1985, p. 6; also see Dorothy Nelkin, *The University and Military Research: Moral Politics at MIT* (Ithaca, NY: Cornell University Press, 1972).

[22] *Kansas City Times*, Jan. 13, 1983, p. A-7.

[23] Chalk, op. cit., p. 13.

[24] As described in, for example, Nicholas H. Steneck, "The University and Research Ethics," *Science, Technology, & Human Values*, vol. 9, fall 1984, pp. 6-15.

[25] *Report of the Committee on Criteria for Acceptance of Sponsored Research in the Faculty of Arts and Sciences* (Cambridge, MA: Harvard University Press, October 1983), p. 3.

[26] Ibid.

[27] Swazey, op. cit., p. 139.

[28] Barbara J. Culliton, "Harvard and Monsanto: The $23-Million Alliance," *Science*, vol. 195, Feb. 25, 1977, p. 759.

Institutional restraints on communication may result not just in suspension of publication but also deliberate, albeit temporary delays. At a 1984 seminar on secrecy in science, many university deans of research remarked that it was not unusual for them to receive requests to delay the submission of a Ph.D. dissertation to University Microfilms, Inc. (a general clearinghouse for U.S. theses and dissertations) and that it was not unusual for graduate schools to cooperate—as a matter of policy—by granting 1-year delays.[30] Typical reasons for such requests were: 1) to allow the student time to seek patent protection, 2) to allow time for first publication in a journal of record, 3) to provide a degree of protection for industrial sponsors of research, 4) to protect the safety and welfare of informants used in the research, or 5) to protect militarily-sensitive information.

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[29] *Science*, Feb. 15, 1985, p. 729.

[30] "Openness and Secrecy in Scientific and Technical Communication," seminar, Vanderbilt University, Nashville, TN, Sept. 24, 1984.

CONTROLS BY PROFESSIONAL ORGANIZATIONS IN SCIENCE AND ENGINEERING

Professional codes or industry association guidelines may act as a regulatory force on the research conduct of members. These rules are voluntary standards that reflect private consensus on public matters. They are enforceable primarily through the social pressure of membership in the association and hence are effective only when such membership is useful or necessary to acquiring or maintaining employment in the field or in acquiring a government grant or contract.

In some scientific fields these rules may form the foundation for State licensing procedures—as in the case of physicians or engineers. In other fields, the codes may pertain to accepted procedures in the field or to testing. The American Psychological Association, for example, has issued guidelines for research psychologists who use animals, as have such groups as the Society for Neuroscience, the Society of Toxicology, and the International Society for the Study of Pain.[31] The American Psychological Association has also developed a set of Ethical Principles in the Conduct of Research with Human Participants. The American Anthropological Association and the American Sociological Association adopted new codes of ethics for research in 1971. The Evaluation Research Society has established professional standards for evaluation research. The American Chemical Society developed the Chemists' Creed and Professional Employment Guidelines, which set standards for practice in research settings. Most scientific societies have, at minimum, guiding principles for the conduct of research. Some have extensive and detailed guidelines for agenda, procedures, and communication of research results.

Recent concern about the leakage of militarily sensitive information to the Soviet Union from the U.S. western allies has led the Federal Government to request the specific cooperation of the scientific and technical societies in regulating communication. The Government has asked societies to restrict access to certain meeting sessions—that is, the session would be neither classified nor open to all meeting participants. The American Association for the Advancement of Science Committee on Scientific Freedom and Responsibility has identified examples of "self-imposed restrictions" in a few professional societies that exclude non-U.S. citizens from meeting sessions dealing with militarily sensitive topics.[32] The Society for the

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[31] *Science*, vol. 228, May 17, 1985, p. 830.

[32] Robert L. Park, "Intimidation Leads to Self-Censorship in Science," *Bulletin of the Atomic Scientists*, vol. 141, No. 3, spring 1985, pp. 22-25.

Advancement of Material and Process Engineering and the Society of Manufacturing Engineers, among others, have voluntarily censored themselves, limiting attendance at their meetings (or at specific meeting sessions) to U.S. citizens only.[33] At least half a dozen professional societies are either reconsidering or reformulating their policies on restricted meetings.*

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[33] Janice R. Long, "Scientific Freedom: Focus of National Security Controls Shifting," *Chemical & Engineering News*, July 1, 1985, p. 9.

*The AAAS is distributing a survey to determine the extent and pervasiveness of this trend.

MECHANISMS FOR GOVERNMENT REGULATION

Federal, State, and local governments use legislation, executive (e.g., Presidential) directives, agency rulemaking, and so forth, to exert control on the conduct and dissemination of research. Such mechanisms differ from entity to entity.

A comparison of two Federal agencies that regulate biomedical research demonstrates how different mechanisms can constrain research. The Food and Drug Administration (FDA) closely monitors drug research and applies its program of control—e.g., in requiring the assurance of consent by subjects involved in clinical trials—uniformly throughout the United States. Tighter requirements for the use of human subjects were instituted in 1962. This organizational approach is tied to FDA's principal mission of regulation aimed at protecting the consuming public; its enforcement power to regulate research comes from the fact that it must approve the marketing, advertising, and distribution of all drugs sold in the United States. The principal regulatory efforts of this agency are thus directed at research in the pharmaceutical industry.[34] In contrast, NIH, as an organization that supports and conducts basic research, applies a philosophy of encouraging academic freedom and imagination in the research it supports through its extramural projects grants program.[35] The NIH approach uses a system of decentralized, institutional review committees that operate under generalized ethical guidelines. NIH also "takes direct responsibility for the protection of research subjects under its own system of national review of project applications."[36] Its principal regulatory effects are felt in the university research labs, although the regulations on molecular biology research or on the use of human subjects in experiments have also been applied to some industry research.

Because of the variety of mechanisms and enforcement in the executive branch agencies, new fields often face a thicket of duplicative or even conflicting requirements. The December 31, 1984, *Proposal for a Coordinated Framework for Regulation of Biotechnology*[37] issued by the Office of Management and Budget is evidence of increasing concern about this problem. In May 1984, the White House Cabinet Council established a working group on biotechnology to review Federal regulatory rules and procedures relating to the biotechnology industry. All three affected agencies (FDA, Environmental Protection Agency, and U.S. Department of Agriculture) would review biotechnology products and processes. Under the *Framework*, review would proceed on a case-by-case basis, each with its own staff, consultants, and expert scientific advisory committees. The Recombinant DNA Advisory Committee (RAC) would continue to oversee rDNA experiments related to biomedical research and the National Science Foundation (NSF) would form a review committee to examine the potential environmental effects of basic research experiments employing rDNA. All five advisory committees would report to a parent committee, the Biotechnology Science Board, which would receive summaries of all recombinant DNA, recombinant RNA, or cell fusion applications and may undertake itself, or request that the agency committee review, a specific proposal. In addition, the Board would evaluate review procedures and committee reports, conduct evaluations of broad scientific issues relating to this research, develop guidelines, and provide "a forum for public concern." As of this writing, NIH is in the process of reviewing comments on the proposed regulations, and no final rule has been issued.

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[34] Alexander M. Schmidt, "The Politics of Drug Research and Development," *The Social Context of Medical Research*, Henry Wechsler (ed.) (Cambridge, MA: Ballinger Publishing Co., 1981), pp. 233-262.

[35] William J. Curran, "The Approach of Two Federal Agencies," *Experimentation With Human Subjects*, Paul A. Freund (ed.) (New York: George Braziller, 1969), p. 449.

[36] Ibid.

[37] 49 *Federal Register* 50856-50907.

Such coordination, is unusual, however. Normally, government regulation of research is administered through a number of uncoordinated and therefore potentially conflicting mechanisms. These include: national or local commissions to review general procedures and policies; tax credits; legislative review and veto; moratoria; controls of acquisition or possession of materials needed for research; interpretation of regulations; contract provisions; and publication or communication review or classification.

Agenda Controls

Governmental Review Commissions

The Government may set up a commission or board to review research, either with an eye to improving research procedures or to resolve some dispute. An example at the local level is the Cambridge Experimentation Review Board, which ruled on the safety of rDNA research in the 1970s at the request of the Cambridge City Council. At a national level, the NIH RAC approves experimental procedures and must consider any proposed changes in the NIH Guidelines for Research Involving recombinant DNA Molecules. The NIH committee, composed of both scientists and nonscientists, meets several times a year to examine special cases of recombinant DNA research, petitions for examption, and proposals for changing the *Guidelines*. The Committee must also recommend to the Director of NIH any proposed change in the guidelines.

National commissions have been used to formulate guidelines for research, but most have not had any power to restrict or delay actual research—e.g., the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established by Congress in 1974 to develop guidelines for such research.

Tax Credits

Legislation offering tax credit or similar financial incentive to encourage and discourage research is passed usually to provide incentives for private funding on designated topics (e.g., research on alternative energy sources). In 1980, Congress gave small businesses and universities the opportunity to obtain patent rights on inventions developed with Federal funds.[38] In response to the energy crisis of the 1970s, over 30 States passed laws to promote solar energy. Most of these laws provide tax incentives (income or property tax reductions) to stimulate private sector research, development, and commercialization of solar systems.[39] Congress has been similarly active in passing legislation that promotes research on alternative energy systems. And the 98th Congress enacted the Orphan Drug Amendments to the Food, Drug, and Cosmetic Act[40] in order to stimulate private research and development (R&D) of drugs for rare diseases.

The Internal Revenue Code also currently allows businesses the option of deducting or amortizing expenditures for research and experimentation over a period of 60 or more months. The Economic Recovery Tax Act of 1981 (Public Law 97-34) provides a 25 percent tax credit for incremental research expenditures made after 1981. That legislation reflects a deliberate attempt by Congress to reduce tax burdens in order to stimulate research. It includes tax credits for laboratory equipment leases, and for portions of payments to universities to perform basic research.[41] These provisions are set to expire at the end of 1985. To stimulate research by private industry, Congress has tried to lower the cost of private R&D through a combination of tax policy, direct spending, and patent legislation.

Social science research was specifically excluded from the areas of research spending for which a tax credit is allowed. Bills introduced in the 98th

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[38] 35 U.S.C. Section 200 (1980).

[39] W. Rogers, *Energy and Natural Resources Law* (St. Paul, MN: West Publishing Co., 1978), p. 31.

[40] 21 U.S.C. Sections 360aa-360ee.

[41] Wendy H. Schacht, "Industrial Innovation: The Debate Over Government Policy," Issue Brief 84004, Congressional Research Service.

Congress, which would have created additional incentives for corporate investment in research and development, also excluded social science research from their definition of "qualified research" for which a corporation may take a tax credit.

The Congressional Budget Office estimates that the Federal Government gives the high-technology research system approximately $1.5 billion in the form of tax credits.[42] There are currently three major tax-related mechanisms that high-tech research industries may employ: 1) straight deductions, year by year, of research expenses such as salaries and equipment [Internal Revenue Code, Section 174]; 2) the R&D tax credit, which expires in 1985 and allows a company to deduct from its taxes 25 percent of amounts that exceed the previous 3-year average of amounts the company spent on research [Public Law 97-34]; and 3) the funding of research through R&D limited partnerships, possible through several provisions of the tax code.

Legislative Review

Congress has several times attempted to control specific research projects or types of projects through legislative review of proposals or projects. In 1975, Representative Robert E. Bauman of Maryland introduced an amendment to the NSF authorization bill (H.R. 4723) which would have allowed Congress to review all NSF proposals prior to the final awarding of the grants. The Bauman amendment passed the House, but was deleted in Senate Subcommittee and therefore not included in the final bill. The strongest argument against the amendment was the burden that would be placed on Congress to review thousands of grants. A second argument was that Members of Congress are not scientists and therefore are not necessarily competent to judge specific research proposals. What might sound frivolous and inconsequential to a layperson can be of major importance to scientific development. A third argument was that consistency would require Congress to oversee the grants made by all other agencies, including the Department of Defense (DOD). Other arguments included the added length of time to receive a grant, the politicizing of the award decisionmaking process, and the possibility of making NSF more conservative (and possibly less innovative) in its effort to please Congress. In 1983, the Supreme Court effectively ruled in *INS* v. *Chadha* (103 S. Ct. 2764) that legislative vetoes, such as proposed in the Bauman amendment, were unconstitutional.

In the 99th Congress, Representative Robert G. Torricelli of New Jersey introduced a bill entitled the "Information Dissemination and Research Accountability Act" (H.R. 1145), which has similar evaluative intent. The purpose of the bill is to "promote the dissemination of biomedical information through modern methods of science and technology and to prevent the duplication of experiments on live animals." It calls for a National Center for Research Accountability, located within the Library of Medicine, which would provide for a comprehensive, full-text literature search before any research proposal involving the use of live animals could be approved. Thus, all animal research proposals would be funneled by the potential granting agency through the Center prior to approval. The President would appoint 20 persons to serve as members of the Center. Critics of the bill claim that the process would unnecessarily prolong the already extensive grants review process and would duplicate the peer review process. In addition, the duplication of research that the bill intends to eliminate is often an important and required aspect of research in that it enhances validity and reliability. Proponents of the bill feel that it will prevent the unnecessary use of animals in research.

Moratoria

The most dramatic device used by government to control research is the legally enforceable ban or moratorium. Moratoria on science—or the proposal of same—are effective ways to focus attention on a serious issue or to express a political perspective that the researchers appear to have been ignoring. The 1974 act prohibiting experimentation on human fetuses (see box B) is an example of such a ban. In 1975, the Department of Health, Education, and Welfare prohibited the funding of research on in vitro fertilization without review by the agency's Ethics Advisory Board.[43]

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[42] Congressional Budget Office, *Federal Support for R&D and Innovation*, April 1984, pp. 76-83.

[43] Michael Gold, "Research Off-limits," *Science 85*, vol. 6, April 1985, p. 36.

Box B.—Fetal Research

The controversy over research on fetuses or fetal tissue illustrates the implementation and effect of various mechanisms for government control of research.

Between 1970 and 1972, advisory groups within the National Institute of Child Health and Development debated NIH policies on the review and funding of human fetal research. Reports of abuses by researchers in other countries had led to pressure on NIH to declare a moratorium on any research with the living fetus before or after abortion, lest such abuses be repeated in the United States. Congressional debate and legislation (National Research Act, Public Law 93-348, Section 2130) created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which produced recommendations that became the core of the Federal regulations. The Commission intended the existing independent, local institutional review boards (IRBs), with the addition of a national Ethics Advisory Board, as the means for control and consideration of fetal research. The fetal research guidelines were adopted as Federal regulations on July 29, 1975, but an Ethics Advisory Board was not chartered until 1977 or convened until 1978, so a de facto moratorium existed during this time on both fetal research and in vitro fertilization.

The Ethics Advisory Board was allowed to die in 1980 and its absence means that the privately supported IRBs are still the only locus of practical control. Supplementing the Federal regulations are 25 State statutes and the Uniform Anatomical Gift Act (passed in all 50 States by 1973). That act governs research on dead fetuses generally by including explicit language to that effect. Department of Health and Human Services (DHHS) regulations cover only DHHS funded research or research institutions; other research is governed by State statutes, when they exist. They range from strict (no research except that of therapeutic value to mother or fetus) to those more liberal than the Federal regulations.[1]

In summer 1974, the National Commission for the Protection of Human Subjects declared a national moratorium on all fetal research, which remained in effect until the Commission issued interim regulations in 1975.

In several cases in Boston in the 1970s, State-level protest also attempted to halt fetal research. Because the research in question used dead fetal tissue obtained from abortion procedures, antiabortion groups charged that publication of findings based on research using such tissue was unethical. In response to the public protest, the 1974 session of the Massachusetts legislature passed "An Act Prohibiting Experimentation on Human Fetuses," which treated such research as a felony offense punishable by up to 5 years in prison. The law (amended in 1976) applies only to fetal tissue and does not prohibit experimentation on live fetuses in efforts that might be considered "beneficial" to the fetus. Many legal scholars consider the law to be imprecise and, because of that imprecision, to have the potential for producing a "chilling effect" on researchers. On the other hand, opponents of the research have pushed for stronger legislation that would make violation a criminal offense. Controversy has continued with the introduction of legislation in Congress proposing a national moratorium on research on live fetuses.

Rules restricting federally funded research on human fetuses, set in place in 1974, specify that individual research proposals must be reviewed by a federally appointed Ethics Advisory Board. When the Ethics Advisory Board was allowed to lapse in 1980, the effect was a de facto ban. No research in this area can be done until it is reinstated. Four succeeding Secretaries of DHHS have failed to limit the moratorium. In January 1984, the NIH sent a request to DHHS for reestablishment of the board, but as of this writing, the Secretary has not acted on the request.

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[1] John C. Fletcher and Joseph D. Schulman, "Fetal Research: The State of the Question," *Hastings Center Report*, vol. 15, April 1985, pp. 6-11.

A moratorium was proposed in 1976 on all R&D surrounding laser isotope separation of uranium. The proposal was to suspend all projects in the United States, "pending the results of efforts to achieve agreement with other industrialized nations to halt their work in this area."[44] The proposers acknowledged the complexity of implementation (and improbability of success) of such a moratorium, but used the proposal itself as a way to further public discussion of the policy on proceeding with the research. The Lilienthal-Acheson proposals in 1946 for regulation of atomic energy would have entailed a similar ban on research in certain sensitive fields.[45]

Controls on Procedures

Acquisition or Possession of Materials Used in Research

Research may be regulated through controls on the acquisition or possession of the chemicals or other substances necessary to do the research. For example, the Environmental Protection Agency (EPA) is authorized by the Toxic Substances Control Act (TSCA) to regulate the approximately 60,000 chemicals subject to the act, at all stages of their development.[46] TSCA recordkeeping and reporting requirements apply to research on chemicals and additional regulatory requirements apply when the chemicals are introduced into commerce.[47]

Federal regulations control the possession, use, and disposal of radioactive substances, including their use in research. Handling of nuclear and radioactive materials is governed primarily by the Nuclear Regulatory Commission (NRC), under the Atomic Energy Act of 1954.[48] The NRC has regulatory power over any materials made in a reactor. It does not have any jurisdiction over accelerator materials or over naturally occurring radioactive materials, although some States do regulate these substances. If the research institution is located within an "agreement" State, the investigator must be licensed by the State radiation control agency. If the institution is within a "nonagreement" State, it must apply to NRC for a license. All research must comply with Federal and State OSHA regulations, which regulate exposure to toxic substances in laboratories.

For research using radioactive substances, then, there are various degrees of licensing and permits, depending upon what is done and the substance in question. Regulatory jurisdiction varies from State to State and between the Federal Government and the State. In addition, there is a tiered system of control based on the quantity of material in question. (NRC has established categorical exemptions from certain regulatory requirements for certain low-level radioactive materials.) The requirements for a license pertain to the personnel and their qualifications, the facility, uses of the material, estimated human exposures, recordkeeping and reporting systems, and disposal practice.[49] Large institutions conducting a lot of research may apply for a broad license, which delegates considerable decisionmaking power to the institution's Radiation Safety Committee. In all cases, radiation safety officers must be approved by the licensing agency and NRC must know and approve the qualifications of such individuals. Most research institutions have a radiation safety officer, even if they do not have a radiation safety committee. Licenses can be very precise, authorizing one investigator to use a specific material for a specific period of time.

There are also regulations for disposal of radioactive waste. All Federal institutions must comply with the Clean Air and Clean Water Act, if applicable. In addition, the institution must apply for a discharge and disposal permit from the State air pollution agency and/or the State water pollution agency. Both Federal and local regulations may apply to disposal as well.

If an institution is found to be in violation of the laws governing radioactive materials, civil monetary penalties can be imposed, and its license suspended or revoked; in addition, the organization would probably receive damaging press coverage. At large institutions, safety precautions may be emphasized, therefore, because of the consequences of a single mistake, primarily the suspension of all of the institution's research using radioactive materials.

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[44] Barry M. Casper, "Laser Enrichment: A New Path to Proliferation?" *Bulletin of the Atomic Scientists,* January 1977, pp. 28-41.

[45] The complete text of the plan was contained in a State Department document, Publication 2498 (1946).

[46] 15 U.S.C. Section 2601.

[47] 15 U.S.C. Section 2607.

[48] See especially Title 10 of the Act.

[49] 10 CFR Parts 30-32.

Department of Transportation regulations enacted under the Hazardous Materials Transportation Act govern shipments of certain research materials (e.g., radioactive materials, etiologic agents, poisons, corrosives, flammables) by requiring specific carriers, containers, or handling practices.[50]

Federal laws prohibiting the possession of narcotics act to restrict research in a number of fields. Researchers who wish to use controlled or illegal substances as a legitimate part of their research must first register with the Department of Justice; they are then investigated by the Drug Enforcement Administration and their research is validated by FDA. If approval is granted, the researcher must request the drug from the National Institute of Drug Abuse. If the research also involves human subjects, additional reporting requirements must be fulfilled. According to the Drug Abuse staff of FDA, the administration of these regulations used to be very time-consuming, but recent streamlining of the approval process and an apparently diminished interest in research involving controlled substances have reduced the number of requests and the time required to process them.

Requirements for Procedural Review Committees

Various Federal and State commissions have been given principal responsibility to implement legal regulations that apply to research procedures—in the case of the rDNA commissions, requirements for physical containment of the biological materials used in the research. By focusing on a very specific step in the research process, the Federal Government was able to establish standards of protection for workers and the community and as well as to set criteria for researcher (and institutional) accountability.[51] Once the rDNA guidelines were set (with the aid of the scientists), the discussion moved back to the sphere of the policymakers and administration officials, who were under political pressure from environmental and public interest groups.

Regulation may also occur at the very end of the research process, as in EPA regulation of field testing of new insecticides or for agricultural research involving rDNA. In a recent case involving insecticide-producing soil bacteria, the EPA has required the company to apply for an experimental use permit and to submit more research data on various aspects of the bacteria (e.g., its longevity in soil and its effect on nontarget species), an action that has the effect of restricting or delaying the use and dissemination of results from the project.

The Federal Government may also require that an institution set up review committees to monitor, approve, and shut down projects. The three principal types are Institutional Biosafety Committees (IBC), Institutional Review Boards (IRB), and Institutional Animal Care and Use Committees.

IBCs are mandated by the NIH *Guidelines for Recombinant DNA Research* and have served as the major locus of responsibility for oversight of that research since 1978. The latest NIH regulations[52] stipulate that an IBC must have "no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research experiments and any potential risk to public health or the environment." At least two members must have no affiliation with the institution apart from their membership on the IBC and should be chosen to represent the interest of the surrounding community with respect to health and protection of the environment. Unless exempt from review under the *Guidelines,* all rDNA research must receive IBC approval. Certain categories of research considered to be of questionable or high risk must be referred to the NIH Recombinant DNA Advisory Committee for approval before work can be initiated. There are currently 301 IBCs registered with the Office of Recombinant DNA Activity of NIH. Approximately 250 are academic IBCs; the rest are industrial. Compliance by industry is voluntary.

"Basic DHHS Policy for Protection of Human Research Subjects"[53] requires that all research involving human subjects conducted by the Department of Health and Human Services (DHHS) or funded in whole or part by a Department grant, contract, cooperative agreement or fellowship, undergo review by an IRB. (See box C.) As with an IBC, IRB membership is specified in the Federal regulations. The IRB must have five members and, per the *Guidelines,* "be sufficiently qualified through experience and expertise of its members, and the diversity of the members' backgrounds including consideration of the racial and cultural backgrounds of members and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects." According to the Office for Protection from Research Risks, the office responsible for the implementation of the IRB regulations, there are currently over 5,000 operating IRBs in the United States. A 1979 study by Jeffrey M. Cohen and William B. Hedberg determined that, in 1 year, a typical IRB was in session 41 times and reviewed 278 proposals, involving approximately 80,000 potential research subjects.[54] That IRB cost the university $36,000 during the year, or about $130 per proposal.

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[50] 49 U.S.C. Sections 1803 et seq. and 49 C.F.R. Parts 100-179.

[51] Dorothy Nelkin, "Threats and Promises: Negotiating the Control of Research," Holton and Morison, op. cit., p. 199.

[52] 49 *Federal Register* 227, Nov. 23, 1984.

[53] CFR 46.

Institutional Animal Care and Use Committees (IUCAC) are required of all institutions that receive Public Health Service (PHS) funds for research involving animals. Under revised PHS policies released May 1, 1985, those committees, which must have lay members, will have the responsibility for reviewing research plans and monitoring compliance. Prior to the establishment of these guidelines, nearly 1,000 institutions already had animal assurances through PHS. It is not known how many new committees will have to be established once the guidelines take effect. The new guidelines also require that all animal facilities must also be accredited by the American Association for the Accreditation of Laboratory Animal Care, a voluntary association that certifies animal handling facilities, or must conduct an assessment based on the NIH *Guidelines for the Care and Use of Laboratory Animals.* Accreditation is a necessary condition if an institution wants to receive PHS funds for research involving animals. By January 1, 1986, each institution receiving PHS funds must submit an "assurance of compliance" (containing such documents as descriptions of the facilities and membership and procedure of the local IUCAC) to the NIH Office for Protection from Research Risks.

Contract Provisions

The provisions of research grants and contracts are used to enforce such things as limitations on spending, allocations of funds among budget categories, requirements that organizations be accredited or meet certain accreditation standards, and requirements that research designs or procedures be approved by the monitoring committees described in the previous section.

In the case of recombinant DNA research, the Asilomar recommendations were adopted by NIH, which then issued a set of guidelines covering research in designated categories. It applied to all recombinant DNA research funded by NIH. Today, the amended NIH *Guidelines for Recombinant DNA Research* set forth the generic requirements for safety in recombinant DNA research. These safety requirements apply through contract provisions to all recombinant DNA research in the United States which is conducted at or sponsored by an institution that receives any support for rDNA research from NIH.[55] Failure to comply can lead to termination of NIH funding or other NIH sanctions. Although limited to institutions funded by NIH, the *Guidelines* have been adopted or followed by virtually all Federal agencies, State and local agencies, and private organizations.

Communication Controls

Reporting requirements in contracts can include regulations on the "deliverables" of a project, usually through prepublication review. Such contractual provisions are currently being invoked in order to restrict the flow of information believed to be linked to national military security or related to the Nation's ability to compete in world markets. Contract provisions have been used, for example, to prohibit foreign nationals from be-

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[54] Jeffrey M. Cohen and William B. Hedberg, "The Annual Activity of a University IRB," *IRB,* May 1980, pp. 5-6.

[55] 45 *Federal Register* 77384, Nov. 21, 1980, and 77409.

Box C.—Research on Human Subjects

Until the 1960s—with the exception of the Nuremburg Code (1947)—there were no legal decisions from the courts and no Federal or State laws concerned directly with how humans were used in experiments (again, with the exception of violations of criminal law). NIH and PHS first began in 1953 to develop formal standards for human experimentation, but these efforts were not productive. The turning point was the increased volume of clinical investigations funded by the Federal Government (the shift in research performer) and government regulation of experimental drugs (manufacturing, distribution, and safety) in interstate commerce through FDA. Another factor was the thalidomide tragedy abroad, which triggered the 1962 Kefauver-Harris Amendments to the U.S. Food and Drug Act. Congress, in debate and not in the original bill, added the requirement to the law that subjects or patients be informed that they were to receive an experimental drug not fully licensed by the Federal Government and that their consent be obtained prior to receiving it. In 1966, the U.S. Surgeon General issued the first PHS Policy and Procedure Order for extramural research on human subjects.[1] This Order required all institutions receiving PHS funds to review projects for the potential of abuse and it led to the formalization of the current system of IRBs.[2]

At present, most categories of human subjects research funded by Federal money or conducted at institutions that receive Federal subsidies are subject to some form of review or regulation. Federal agencies with oversight in this area specifically list those categories that are exempt or not subject to regulation; but, research conducted without direct or indirect Federal funding is not subject to human subjects regulations. In addition, some populations may not be adequately protected by existing regulations.

All research funded in whole or in part through DHHS by direct award, cooperative agreement, or fellowship, then, is subject to human subjects regulations [45 C.F.R. 46, Section 46.101]. Indirectly, all research conducted at or sponsored by institutions which do not receive DHHS funds are not legally required to comply, but according to Charles McKay, of the NIH Office for Protection from Research Risks, 96 percent of the 500 major institutions conducting research apply DHHS regulations to research not funded by DHHS. Compliance is indicated through a statement of assurance. Regulations of FDA cover clinical investigations with regard to products specified in the Food, Drug, and Cosmetic Act for marketing. These include drugs, biologicals, blood and blood products, devices, and food additives. In addition, the U.S. Department of Agriculture (USDA) regulates clinical investigations of food additives. For the Department of Defense, the Veterans Administration, and 20 other agencies, varying degrees of regulations are tied to direct or indirect use of their funds. All use IRBs and informed consent practices. There is an effort underway by the Office of Science and Technology Policy—and near completion—to have cross-agency uniform regulations very similar to the existing DHHS regulations.

Despite these efforts, research on human subjects does take place under conditions or in institutions exempt from DHHS regulation. DHHS itself exempts educational research, test development, interview and observation research, and research involving specimens and/or medical records, as long as the information taken from these sources is recorded in such a manner that subjects cannot be identified or that the information revealed would place the subject at risk. The Department of Justice has exemptions in their coverage of prison research, and has legal prohibitions against regulation of research on recidivism and probation. The Department of Defense exempts epidemiological research from regulation. Industrially related research (e.g., academics doing consultative work designing systems to improve worker efficiency) is not subject to regulation. All product marketing research (testing of products not FDA or USDA regulated) is exempt from DHHS regulations; some of it is covered by consumer safety laws, but those only apply after the product is on the market. Moreover, the regulatory intent is to protect the public rather than the subjects.

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[1] Judith P. Swazey, "Protecting the 'Animal of Necessity': Limits to Injury in Clinical Investigation," *Limits of Scientific Inquiry*, Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), p. 138.

[2] William J. Curran, "The Approach of Two Federal Agencies," *Experimentation With Human Subjects*, Paul A. Freund (ed.) (New York: George Braziller, 1969).

One of the solutions to criticism has been to sharpen the procedures for ensuring that subjects have knowingly and willingly consented to participate in an experiment. There is now an extensive body of law and regulatory controls, and literature, debating the social and moral aspects surrounding the question of informed consent to human experimentation. Today, the United States regulates research to protect the physical or psychological health or the privacy of the human subjects used in research under guidelines established by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The National Research Act of 1974 instructs the Commission to: 1) "identify the basic ethical principles which should govern research involving human subjects and to recommend guidelines and mechanisms for assuring that such principles are observed; 2) "to clarify the requirements of informed consent to research in the cases of children, prisoners, and the institutionalized mentally infirm;" and 3) "to investigate the use of psychosurgery and recommend policies for its regulation."

ing employed on a research project.[56] More recently, the Federal Government has used grant and contract terms as a means of directly controlling dissemination of research results,[57] by requiring that the researcher or institution allow prepublication review by the sponsoring or interested Federal agency. Contracts for classified work, of course, routinely include such provisions but some agencies have begun to invoke prior approval provisions previously considered to be *pro forma* (or have considered revising their standard contracts to include such provisions). The purpose of requested delays or review is to allow the opportunity for either classification or alteration (editing and censorship).

In one such case in 1980, NSF refused to fund parts of a cryptology proposal submitted by a computer scientist because of the national security implications of his work. A later decision awarded the funds to the researcher with the stipulation that he take responsibility for seeking prior constraint as required by the content of his work. NSF eventually drafted new language for all its contracts to require that a grantee take responsibility for notifying the cognizant NSF Program Director if data, information, or materials developed in the course of research appear to require classification. NSF retains the option—after review of the information—to defer dissemination, distribution, or publication.

The mechanism of classification (or the threat of the possibility of classification) can also be used to delay publication. This tactic has been used by the National Security Agency to delay journal publication of a number of scientific articles on cryptography.[58] From 1982 to 1985, Federal regulations on the export of technical information have been used to bar certain foreign nationals from attending otherwise open society meetings and have been used to require researchers to withdraw unclassified technical papers scheduled for presentation at professional society meetings because foreign nationals might attend those meetings.[59]

In addition to contract provisions, there are nine major legal mechanisms by which the U.S. Government can restrict formal and certain informal communication of scientific and technical information.

1. **The Arms Export Control Act of 1976** and the resulting International Traffic in Arms Regulations and U.S. Munitions List, administered by the Department of State, authorize control of the export and import of defense articles and defense services, including export of technical data related to defense articles.

2. **The Export Administration Act of 1979,** implemented through the Export Administration Regulations, Commodity Control List (CCL), and Militarily Critical Technologies List (MCTL), and administered by the Department of Commerce,

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[56] *Scientific Freedom and National Security,* Issue 5 (Washington, DC: American Association for the Advancement of Science, March 1985), p. 7.

[57] *Interim Report of the Committee on the Changing Nature of Information* (Cambridge, MA: Massachusetts Institute of Technology, Mar. 9, 1983), Section 4.5.

[58] Ibid.

[59] *Free Trade in Ideas: A Constitutional Imperative* (Washington, DC: American Civil Liberties Union, May 1984); Long, op. cit., see especially the table of meetings that have been restricted.

authorizes control of the export of tangible goods, including technical data, in the interest of national security and foreign policy and, to a lesser extent, to protect the domestic economy. MCTL designates arrays of technical information, expertise, or equipment that DOD believes would make a significant contribution to the military potential of another country if exported. The unclassified version of this list is over 200 pages long; the classified is reported to be over 700.[60] Both the CCL and the MCTL were not intended to be control documents, but rather to be reference lists of the sensitive technologies.

3. **Executive Order 12356 of 1982** authorizes classification of information, including that pertaining to "scientific, technological, or economic matters," that is "owned by, produced by or for, or is under control of U.S. government" for national security purposes. The order contains a specific exemption for "basic scientific research information not clearly related to national security."

4. **The Atomic Energy Act of 1954,** as amended, places explicit controls on scientific information and defines restricted data. The act is not limited to nuclear physics nor even to activities of the Federal Government; its language is sufficiently broad to allow the extension to "privately generated" knowledge as well. A 1981 amendment allows the Secretary of Energy to adopt regulations on the dissemination of unclassified information regarding either the design of facilities or their security measures.[61]

5. **The Invention Secrecy Act of 1951** authorizes the defense agencies to review applications submitted to the Patent and Trademark Office and, if publication of the patent is deemed harmful to national security, to declare the invention secret for a period of 1 year (with restriction annually renewable). The justifications for the Invention Secrecy Act (1951) are to allow defense agencies to review applications for patents submitted to the Patent and Trademark Office, with the goal of catching inadvertent violations. If publication of a patent is judged to be potentially harmful to national security, then a 1-year, renewable secrecy order is issued.[62]

6. **The Freedom of Information Act** contains provisions allowing but not requiring agencies to exempt certain types of information from mandatory disclosure.

7. **Executive Order 12333 on Intelligence,** issued December 4, 1981, allows for the covert collection of information by agents posing as academics.

8. A number of DOD directives on national security and classification based on 10 U.S.C. 140c allow that agency to restrict information developed by scientists under DOD contract. **Directive 5230.25** outlines the conditions under which DOD can withhold classified data from general public dissemination in accord with export control laws. An October 1984 memorandum on "**Publication of the Results of DOD sponsored Fundamental Research**" sets forth policies on publications. And **Directive 5230.24** (November 1984) requires all newly created technical documents in DOD to carry statements defining distribution and indicating how requests for the document should be handled.

9. **The Immigration and Nationality Act** may be used to refuse admission to or deport foreign scholars from U.S. research activities.

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[60] Long, op. cit.

[61] Harold C. Relyea, "Shrouding the Endless Frontier—Scientific Communication and National Security: The Search for Balance," *Striking a Balance: National Security and Scientific Freedom,* Harold C. Relyea (ed.) (Washington, DC: American Association for the Advancement of Science, 1985), p. 85.

[62] Ibid.

THE ROLE OF THE COURTS IN THE REGULATION OF RESEARCH

Statutory law governs the role that the judicial branch may play in the regulation of research: the courts respond to and interpret existing government action. The Federal courts have no jurisdiction other than to interpret the laws enacted by Congress or regulatory actions taken under Federal, State, or local statutes.

The courts have frequently been used, however, in environmental disputes to require Federal agencies to perform, commission, or use research to support environmental policy decisions. The intent—through lawsuit—has been to force the agencies to increase or, in some cases, to improve their use of research. The effect, at least in the 1970s, was to strengthen the quality and increase the amount of environmental science research. Environmental lawsuits are, however, just part of a general shift in the use of the judicial system to affect social policy.[63] More dramatic use of the courts occurs when, after a plaintiff has filed suit, the court issues an injunction that prohibits the research from going forward at all. In the case study presented in chapter 7, the Supreme Judicial Court of the Commonwealth of Massachusetts at first issued a temporary restraining order against a municipal public health order that had attempted to stop research at a local laboratory; that court later ruled to uphold the city's right to impose such a ban.

In May 1984, Federal District Judge John Sirica, in effect, put a moratorium on all field tests of genetically modified microbes being conducted by the University of California.[64] The experiments in question involved tests of genetically engineered bacteria (Pseudomonas syringae) designed to prevent frost formation on plants. In September 1983, a group of plaintiffs led by Jeremy Rifkin and the Foundation on Economic Trends claimed that NIH was violating National Environmental Protection Act (NEPA) requirements for an environmental impact statement. NIH claimed that its approval process more than satisfied the NEPA requirements.[65] On April 12, 1984, Rifkin filed a motion for injunction to prevent the researchers from proceeding with a field test experiment scheduled for May. On May 16, Judge Sirica granted the motion for a preliminary injunction and ordered that: 1) NIH be enjoined from approving experiments involving the intentional release of recombinant DNA, and 2) that the University of California be enjoined from proceeding with the experiment until final resolution on the case. In subsequent court action, the U.S. Court of Appeals for the District of Columbia ruled (February 27, 1985) that experiments could proceed if their potential environmental effects were properly evaluated. NIH must now prepare environmental assessments.

Recently, an additional legal action has introduced controversy into what has usually been a quiet region of the scientific community, agricultural research. In 1979, attorneys filed a lawsuit, on behalf of 17 farm workers and the California Agrarian Action Project, that charged the University of California with unlawfully spending public funds on mechanization research that displaced farm workers.[66] (For a full description of the case, see app. A.)

MECHANISMS FOR SOCIAL CONTROL OUTSIDE OF GOVERNMENT

Public opinion can be a potent force for pressuring government to enact regulation or enforce more stringently existing rules. It is most often expressed through the mechanisms of public meetings, picketing, protest, violence, or political action organizations. For example, recent activities by animal rights organizations have included break-ins, vandalism, and theft of animals, data and equipment from laboratories using animals in their research; in some cases, direct threats have been made to the lives and safety of investigators and their staff. More moderate groups have used the traditional policy arena to seek change, lobbying Congress and State legislators for stricter laws. In summer 1985, DHHS Secretary Margaret Heckler suspended funding for a head trauma study utilizing anesthetized baboons at the University of Pennsylvania after members of the Animal Liberation Front (ALF) illegally raided the University lab, stealing videotapes and destroying equipment. DHHS officials contend that while the research protocol was considered to be scientifically justifiable, the laboratory had violated its animal welfare assurance to NIH, and that the decision to suspend funds was unconnected to the sit-in conducted by ALF at the NIH Bethesda Campus.

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[63] Donald L. Horowitz, *The Courts and Social Policy* (Washington, DC: The Brookings Institution, 1977).

[64] Marjorie Sun, "Rifkin and NIH Win in Court Ruling," *Science*, vol. 227, Mar. 15, 1985, p. 1,321.

[65] Judith A. Johnson, "Recombinant DNA: Legal Challenges to Deliberate Release Experiments," U.S. Congress, Library of Congress, Congressional Research Service, Science Policy Research Division, report No. 85-502, Jan. 7, 1985.

[66] Philip L. Martin and Alan L. Olmstead, "The Agricultural Mechanization Controversy," *Science*, vol. 227, Feb. 8, 1985, pp. 601-606.

A number of church groups, in the United States and abroad, have recently provided an additional mechanism for expression of social control on research. Through conferences, newsletters, and "pastoral letters," religious organizations have attempted to educate their members, raise public awareness about the theological and ethical dilemmas posed by research, or to sway public action concerning regulation of specific areas of research. In 1979, for example, the World Council of Churches sponsored a World Conference on Science, Faith, and the Future at which scientists, theologians, trade unionists, businessmen, and politicians met to discuss the nature of science and of faith. More recently, the Episcopal Diocese of Massachusetts convened a Biotechnology Study Group to develop a study guide for use in churches. The guide addresses the implications of new developments in gene therapy, genetic engineering, and fetal research. Theologians have also taken more direct approaches in registering their concern, such as the 1983 "Theological Letter Concerning the Moral Arguments Against the Genetic Engineering of the Human Germline Cells," a letter signed by representatives of virtually every major church organization in the United States. Most recently, the House of Bishops of the Episcopal Church adoped an official position on genetic engineering that "encourages . . . research directed to an increase in human understanding of vital processes, recognizing that human DNA is a great gift of God . . ."[67] In addition, the Bishops asked that Congress ensure that FDA or an appropriate agency seek advice from ethicists and the lay public to assure that use of genetic engineering is ethically acceptable.[68]

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[67] Cited in *Science*, vol. 230, No. 4724, Oct. 25, 1985, p. 423.
[68] Ibid.

SUMMARY

There have always been measures of control imposed on the scientific community. Most often the controls have been in the form of self-restraint, imposed by the scientific community through peer review and peer pressure. These controls have been shaped by scientific and technological criteria as well as by the social values and norms apparent in the ethical codes and standards adopted by most scientific societies. It is only recently in the history of science that so many institutions and social forces have influenced in so many ways the conduct of science.

As described in this chapter, research can be directly controlled at all stages of the scientific process. Forces can affect the agenda, the process, and the dissemination of results. These forces can be exerted informally, through professional and peer pressure; formally, through institutional mechanisms; or legally, through Executive orders, legislation, and agency rulemaking. Finally, the courts can be used as a mechanism for interpretation of legal controls.

The value of this "cobweb" of direct control lies in its democratic and pluralistic nature. The danger of this system, however, lies in the potential for uncoordinated and potentially conflicting mechanisms for direct control. The potential complexity of this approach to regulation may be exacerbated when compounded by the many levels and forms of indirect control of research, to be examined in chapter 5.

Chapter 5

Mechanisms for Indirect Control of Research

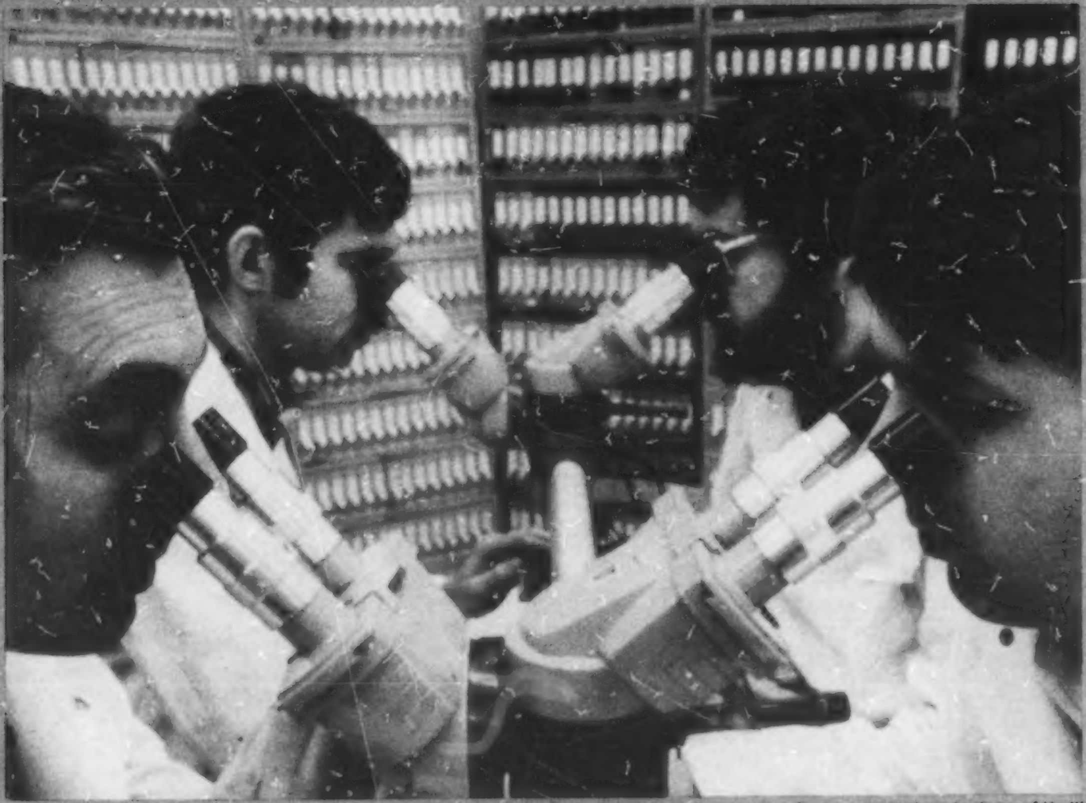

Photo credit: National Institutes of Health

Chapter 5

Mechanisms for Indirect Control of Research

Research can often be as effectively restrained by the secondary or tertiary impacts of laws or policies intended to do something else as by deliberate imposition of regulatory law or policy. Governmental activity can control the nature and direction of science even when regulations would seem to have very little to do with regulating the scientific enterprise.[1] In fact, many of the constraints that have been most burdensome to research institutions—both financially and administratively—were not intended to affect the substance of scientific work. Such constraints as the clerical and managerial burdens of social security taxes, equal opportunity and affirmative action requirements, environmental protection, or occupational health and safety "limit the autonomy of administrators and the freedom of research workers."[2] Research institutions that do not question the importance of such general domestic policy actions may nevertheless question the use of research grants or contracts and in particular the withholding of Federal funds in order to force an institution to comply. They argue that constraints are imposed not to sustain or ensure the quality of research but in an effort to secure "short-term practical results, regional distribution of funds, and other criteria more or less irrelevant to scientific excellence."[3] In these cases, science has not been so much singled out for regulation as caught up in society's growing willingness to regulate all kinds of specialized institutions and activities.[4]

The most pervasive control on the scientific agenda is, of course, the supply of money, but that control is uncoordinated. Such influences are more likely to result in what historian Melvin Kranzberg terms a "shotgun approach" to regulation via funding. This situation occurs when, in response to a new government program directed at a narrow topic (e.g., some form of cancer), researchers alter their research descriptions in order to obtain funding for basic or arcane research they are already pursuing.

This chapter looks at some examples of government laws or actions that, without so intending, appear to be exerting some regulatory influence on research. They can be distinguished from the forces discussed in chapter 4 by the fact that they are not *intended* to restrain or inhibit the process of scientific research. This chapter addresses first those forces that act both at the project and the institutional level through the grant and contract funding mechanisms of the Federal Government. Such restraints were among those most frequently mentioned in OTA's survey of university administrators and laboratory directors. A second type of restraint results from the implementation of legislation or rulemaking related to social programs, such as antidiscrimination statutes or privacy legislation, and from occupational and public health and safety legislation.

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[1] Melvin Kranzberg, Georgia Institute of Technology, personal communication, 1985.

[2] Don K. Price, "Endless Frontier or Bureaucratic Morass?" *The Limits of Scientific Inquiry*, Gerald Holton and Robert S. Morison (eds.) (New York: W.W. Norton & Co., 1979), pp. 75-92.

[3] Ibid., pp. 75 and 81.

[4] Harvey Brooks, Benjamin Peirce Professor of Technology and Public Policy, Harvard University, personal communication, 1985.

ADMINISTRATIVE REQUIREMENTS ON UNIVERSITIES THAT ACCEPT FEDERAL GRANTS OR CONTRACTS

In the last 40 years, rules governing the research grant system, the procedures for assuring accountability in the administration of such grants, and the system of Federal support to higher education in general have placed ever more administrative and legal requirements on the universities.[5] These requirements have stimulated considerable antagonism and hostility because many university administrators have seen it as an intrusion into their autonomy. In the 1970s, Steven Muller expressed these feelings during congressional testimony when he called for universities to:

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[5] David Dickson provides some discussion of the larger issues in *The New Politics of Science* (New York: Pantheon Press, 1984).

> . . . resist the tendency of the federal government to attach a growing body of regulations and conditions to its measures of support for higher education. . . . At stake is the essential need of the university to maintain the unfettered freedom of the human mind to apply its powers and methods of reason.[6]

To many observers, relations between the government and the universities appear to have deteriorated over the last decade; they attribute this change to policies and practices inherent in Federal support of research. These policies act as a form of indirect regulation on research. Under most conditions, Robert Sproull observes:

> . . . the principal investigator does not feel the weight of this pyramid on his back. Although no one has ever calculated how much more research could be supported if this towering apparatus was made leaner, the investigator can frequently ignore it all. There is a growing intrusion, however, into the control of an investigator's research.[7]

A major change in public control of science—and a handle for enforcing regulation—has been the increased requirement for financial accountability imposed by the Federal Government. The post-war "contract" between government and science allowed scientists, through the process of peer review, to make decisions about the allocation of government funds to specific projects, but required that universities be accountable fiscally to the government. The universities do not argue over the need for accountability, rather about how it can be accomplished. This indirect regulation derives in part from the retroactive application of increased standards and from the interpretations applied to key principles contained in indirect cost calculation, and Office of Management and Budget (OMB) Circulars A-21 and A-110.

Indirect costs. Donald Kennedy, President of Stanford University, has referred to the university-government indirect cost reimbursement system as "the basic fabric of understanding and trust that has supported science for 30 years."[8] During those decades, "government policy has held indirect costs to be an entirely legitimate part of total research costs," but as these cost rates have increased, and the resources for research at the Federal level have become more constrained, the rates—and the accounting necessary to calculate them—have become an increasing source of tension. Many university administrators and scientists argue that the process of including an indirect cost rate in a research proposal significantly affects research because it can act to array a principal investigator and his/her sponsor or granting agency against the institution—a polarization that is "damaging to morale and, ultimately, to research."[9]

Indirect costs are paid as grant overhead to institutions to cover maintenance, administrators' salaries, and other operating expenses. A 1984 General Accounting Office (GAO) Report calculated that, in the last decade, indirect costs have increased so much that they now account for about 30 percent of all National Institutes of Health (NIH) extramural grant expenditures (up from 21 percent in 1972).[10] Each institution receiving a grant negotiates its rate. The Department of Health and Human Services (DHHS) may audit an institution to determine whether indirect cost claims are valid. OMB's Circular A-21 "Cost Principles for Educational Institutions" lists allowable categories of indirect costs. Government rules allow for the varying circumstances of institutions, but they do require that methods used for calculations be consistent with sound accounting principles. The disagreement over the reality of indirect costs, and what the costs of research should include, form a major part of the problems surrounding this topic.

Indirect cost rates are based on the most recent actual expenditures for indirect costs. The costs rates are recomputed annually and submitted to a granting agency for evaluation, which uses one of two main systems for determining and reimbursing indirect costs. The NIH requires that principal investigators submit proposals that specify only the direct costs of the research proposed. Peer reviewers see only the direct cost budget. A separate award is made to the institution for indirect costs. Other agencies, such as the National Science Foundation (NSF), the Department of Defense (DOD), and the National Aeronautics and Space Administration (NASA), require that proposals include both direct and indirect costs, and reviewers see the complete budget. If an award is made, the approved budget must be based on the last negotiated indirect costs rate for the institution on the grant. If this rate is out of date (as can occur), then rising indirect cost rates can limit the funds available to a researcher on a project-by-project basis.

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[6] Steven Muller, "A New American University," testimony before the U.S. Congress, House Committee on Science and Technology, published as *National Science and Technology Policy Issues*, 1979.

[7] Robert L. Sproull, "Federal Regulation and the Natural Sciences," *Bureaucrats and Brainpower: Government Regulations of Universities*, Paul Seaburg (ed.) (San Francisco, CA: Institute of Contemporary Studies, 1979), p. 72.

[8] Donald Kennedy, "Government Policies and the Cost of Doing Research," *Science*, vol. 227, Feb. 1, 1985, p. 482.

[9] Sproull, op. cit.

[10] National Academy of Sciences, *Strengthening the Government-University Partnership in Science* (Washington, DC: NAS, 1983), p. 129.

As indirect cost rates rise, research budgets buy less. Some researchers "consider payment of indirect costs a subsidy for higher education and a diversion of support for research."[11] University administrators, however, see indirect cost recovery as essential to maintaining the research infrastructure.

Budget Circulars A-21 and A-110. Relations between the universities and the Federal Government were strained considerably in 1979 as a result of revisions to OMB Circular A-21 (Cost Principles for Educational Institutions). In order to allocate indirect costs, the universities were required to institute "time and effort" reporting for employees whose salaries were charged in any part to the research grant. The rule required faculty to account for 100 percent of the time for which they were compensated, regardless of the fraction devoted to federally supported work. Although the OMB believed these procedures to be necessary to determine if research funds were being used for the purposes designated by Congress, academic scientists considered them a violation of their autonomy. Emotions ran high. A. Bartlett Giametti, President of Yale, proclaimed: "Never have I seen the lash of federal regulations applied to a crucial area of the nation's intellectual life with such seeming indifference to financial and human consequences."[12] The stringency of these OMB requirements has since been relaxed somewhat. In fall 1982, for example, DHHS awarded 22 contracts to large universities to test a procedure whereby coordination audits would be carried out by public accounting firms and university auditing staff. For research administrators, this change meant added responsibility and the imposition of a cost previously borne by the Federal granting agency, but it allowed the independent auditors to conduct an audit that better reflects the research environment in the institution under investigation. This single-audit concept, now allowable for all grantee institutions under 1982 revisions to Circular A-21, provides for greater flexibility in university reporting of time and effort. Some universities, Yale University and Stanford University, in particular, have negotiated agreements with OMB that allow them to eliminate time and effort reporting for the time being.[13]

Concerns about the regulatory nature of the Federal grant relationship date back to the 1960s. A U.S. Commission on Government Procurement—set up in response to widespread concern about grants and contracts administration rules—found that procurement-type Federal controls were being inappropriately applied to grant-type assistance relationships. The Commission's recommendations to deal with this problem were implemented eventually in the Federal Grant and Cooperative Agreement Act of 1977 (Public Law 95-224), which distinguished Federal assistance from Federal procurement and required that grant relationships entail minimal government involvement in grantee affairs. However, OMB guidance issued to implement the act failed to require that Federal agencies use the grant in the fashion envisioned by the act, thereby vitiating its regulatory-reducing effect.[14]

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[11] U.S. General Accounting Office, *Assuring Reasonableness of Rising Indirect Costs on NIH Research Grants—A Difficult Problem* (Washington, DC: 1984).

[12] See discussion of these agreements in *Report of the Workshop on the Effort Reporting Requirements of OMB Circular A-21* (Washington, DC: National Academy of Sciences, 1984).

[13] Quoted in Dickson, op. cit., p. 98.

[14] Robert Newton, National Science Fooundation, personal communication, 1985.

In the late 1970s, the National Commission on Research concluded that the administrative and fiscal controls used by Federal agencies in the support of academic research interfered with the conduct of research. During the same period, NSF and the Association of American Universities conducted an experiment in grant administration that resulted in NSF delegating to grantees the responsibility for administering most Federal controls. More recent discussions have focused on problems caused by discrepancies between Federal rules, and so there are proposals now for a simplified and standardized Federal approach to the support of academic research. Such an approach might reverse or remedy the fragmentation of research programs caused by multiple sources of Federal support, might reduce overall research costs, and might increase research productivity. Federal administrative and accounting rules might begin to match the realities of how research is conducted. One way would be to recognize the researcher's program of research as the administrative and accounting unit. Under the aegis of the National Academy of Sciences Government-University-Industry Research Roundtable, a Federal effort is being undertaken to demonstrate such a simplified arrangement, including a demonstration project for the Federal support of academic research in Florida.

PROTECTIVE LEGISLATION AND AGENCY RULEMAKING

Antidiscrimination Statutes

Several statutes bar recipients of Federal financial assistance from excluding persons, because of their color, race, sex, or national origin, from participation in federally supported activities. These antidiscrimination statutes apply to recipients of NSF and NIH grants and compliance must be assured prior to receipt of funds.

Section 602 of the Civil Rights Act of 1964 requires Federal agencies and programs to issue regulations implementing Title VI of the Civil Rights Act. The act provides that no person shall, on the grounds of color or national origin, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity receiving Federal financial assistance. These regulations are also applicable to sub-grantees, contractors, and subcontractors of a grantee. Grant applicants must issue an "Assurance of Compliance" to be filed with the agency.* Similar assurances must be filed by the grantee to assure compliance with the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

Title IX of the Education Amendments of 1972 prohibits the exclusion of persons on the basis of sex from any education program or activity receiving Federal financial assistance. NSF interprets this to apply to grants under their Science Education Programs but not to grants for scientific research. Public Health Service (PHS) grantees, however, are required to submit an assurance to the Office for Civil Rights, Office of the Secretary, DHHS, before a grant, sub-grant, or contract under a grant may be made. In addition, all PHS grantees are encouraged to "adopt practices that will eliminate sex discrimination and encourage sex fairness, including but not limited to, using language that represents both genders, avoiding sex stereotyping, and representing women equitably in leadership and policymaking positions."

Small Business Innovation Research Programs and Use of Services Regulations

Federal research funding and how the grantees use those funds are subject to laws and guidelines that are intended to promote opportunities for small businesses and minority-owned businesses, and to favor American businesses over foreign interests. Under Public Law 97-219 (the Small Business Innovation Development Act) each agency with a qualifying research and development (R&D) budget in excess of $100 million must establish a Small Business Innovation Research Program (SBIR). Each agency must set aside 1.25 percent of its extramural R&D obligations for its SBIR rogram. The SBIR program is intended to pro-ide a mechanism for opening up Federal R&D pportunities for small high-technology firms. The Departments of Agriculture, Energy, Trans-ortation, and Interior; the National Research Council; the Environmental Protection Agency EPA); DOD; DHHS; NASA; and NSF are all re-uired to participate in this program. In addition, unds flow indirectly to small firms through the ubcontracting requirements of Public Law 95-07, which requires that large prime contractors nust subcontract part of their Federal work to mall firms.

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*See National Science Foundation and National Institutes of Health Grant Policy Manuals.

Executive Order 12138 of 1979 establishes a na-ional program to foster the role of women in busi-ess, by encouraging preference in procurement nd the deposit of Federal funds. Executive Or-ler 11625 of 1971 strives for the same goals for ninority-owned businesses. Recipients of NSF rants are also encouraged, but not required, to se banks owned at least 50 percent by minority roups or women. In addition, according to the nternational Air Transportation Fair Competi-ive Act of 1974, grantees must use a certified U.S. lag carrier for foreign transportation of persons r property, for purposes of the research, unless ot available.

Privacy Legislation

The Privacy Act of 1974 (Public Law 93-579) rovides certain safeguards for individuals against invasions of personal privacy. These include: 1) the right of individuals to determine what information about them is maintained in Federal agencies' files and to know how that information is used; and 2) the right of individuals to have access to such records and to correct, amend, or request deletion of information in their records that is inaccurate, irrelevant, or outdated.[15]

The act imposes requirements on Federal agencies with respect to the manner in which they collect, use, disseminate, and maintain records containing information pertaining to specific individuals. Thus, information obtained for one purpose cannot be used for other purposes without the consent of the concerned individual. This regulation applies to records maintained by PHS with respect to grant applications, grant awards, and the administration of grants, as outlined in DHHS regulations that implement the Privacy Act.[16] Records maintained by grantees, however, are not subject to these regulations.

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[15] Public Health Service, "Grants Policy Statement," December 1982, p. 15.

[16] 45 CFR 5b.

ENVIRONMENTAL LEGISLATION

Until the end of 1984, EPA regulations for the ontrol of hazardous wastes under the Resource Conservation and Recovery Act (RCRA)[17] had imited influence on some research activities, be-ause they established regulatory exemptions for 'small quantity" generators[18] but held all other enerators subject to the full range of regulatory equirements. To avoid regulatory costs and other urdens, many research institutions sought to stay vithin EPA's limit for small quantity generators. Chemical associations also promoted the concept and practice of waste stream reduction in process industries and laboratories.[19] In November 1984, amendments to RCRA severely limited these exemptions by requiring EPA to regulate generators of as little as 100 kilograms a month.[20] It will be more difficult for research facilities to avoid RCRA regulations in the future.

Other laws administered by EPA have led to further unintentional regulations of research activities. Research laboratories that emit air and water pollutants are subject to EPA regulations under the Clean Air Act[21] and the Clean Water Act,[22] as well as corresponding State statutes. Researchers will have to secure permits and comply with EPA *and* State permit restrictions on the discharge of these pollutants. These "end-of-pipe" emission restrictions can influence the research process significantly, especially when the research involves highly toxic substances.

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[17] 42 U.S.C. Sections 6901 et seq.

[18] 40 CFR Part 261.

[19] See *Less Is Better: Laboratory Chemical Management for Waste Reduction* (Washington, DC: American Chemical Society, 1985).

[20] 42 U.S.C. Sections 6931(D), added by Public Law 98-616 (1984).

Laboratory research in industry, universities, and government may also be affected by such things as EPA regulations on disposal of hazardous waste, health regulations set by the State or city in which the laboratory is located, and regulations on handling nuclear and other hazardous substances.

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[21] 42 U.S.C. Sections 7401 et seq.

[22] 33 U.S.C. Sections 1251 et seq.

OCCUPATIONAL AND PUBLIC HEALTH AND SAFETY REGULATIONS

As will be illustrated chapter 6, government regulations intended for business and industry can have quite different effects when applied to laboratory-based, university research activities. Richard W. Lyman has observed that "universities are not quite the uniquely subtle and complex organisms they like to consider themselves, but they do possess a good many characteristics that make regulations suitable to a steel mill not always relevant or appropriate [to a university]."[23] Most of these regulations are of two types: regulations designed to apply to production, or pilot plant activities and regulations aimed at achieving some social goal.

Some observers propose that, in principle, the cost imposed on various economic or research activities by regulation should be proportionate to the potential environmental, health, or safety impact of these activities; but others disagree sharply with the argument that such regulation takes industrial financial resources away from research, and cite a lack of evidence for those effects.[24]

The protection of worker health is required by such legislation as the Occupational Safety and Health Act,[25] by the Occupational Safety and Health Administration (OSHA), and by other regulations.[26] The act concerns the general duty of employers to provide safe working conditions for their employees and for employer compliance with OSHA regulations. The regulations limit worker exposure to various physical, chemical, and other agents and hazards to health and safety, such as noise, radiation, or toxic chemicals. In addition to requirements for recordkeeping, medical surveillance, and monitoring, the regulations also set forth, on a generic basis, employee rights to request OSHA inspections and to obtain access to medical records, exposure records, and labels on hazardous chemical containers.

Right-To-Know Legislation

The need for people to obtain information on the risks they run by working with hazardous chemicals has recently prompted more specific legislation, which could have a significant unintended regulatory impact on research laboratories, especially those based in universities. Although current Federal regulations in this area do not apply to such laboratories, the recent State and proposed Federal "right-to-know" legislation could have the secondary effect of creating new controls on university laboratories. These laboratories work with hundreds of chemicals in an experimental situation or do research *on* hazardous chemicals.

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[23] Richard Lyman, quoted in Seaburg, op. cit.

[24] Brooks, op. cit.; for a general discussion of the effect of health and safety regulation on R&D, see, for example, Nicholas Ashford and George Heaton, "Regulation and Technological Innovation in the Chemical Industry," *Law & Contemporary Problems,* vol. 46, No. 3, summer 1983, pp. 109-137; also see Nicholas Ashford, et al., "Using Regulations to Change the Market for Innovation," *Harvard Environmental Law Review,* vol. 9, No. 2, 1985.

[25] 29 U.S.C. Sections 651 et seq.

[26] 29 CFR Part 1900.

In November 1983, OSHA issued a "hazard communication" rule,[27] which establishes that workers in the manufacturing industry have a right to know about the chemical and physical hazards in their workplaces. Manufacturers and importers of hazardous chemicals, and their customers who use the chemicals in subsequent manufacturing activities, thus have disclosure duties under the rule.

The rule initially requires that manufacturers and importers of chemicals provide their customers with labeled containers and a Material Safety Data Sheet (MSDS) for each purchased chemical that has been determined to be hazardous. It also requires that all firms in the manufacturing sector—both "downstream" customers and chemical manufacturers themselves—institute hazard communications programs to provide information to and train workers who could potentially be exposed to the chemicals.

The rights created by the OSHA rule do not currently extend to workers in research laboratories that are not within the manufacturing sector. For research laboratories within the manufacturing sector, however, employers must:

- ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;
- maintain any MSDSs that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory workers; and
- provide laboratory workers with information and training on hazardous chemicals in their work areas at the time of their initial assignment, and when a new hazard is introduced into their work area.

Chemical manufacturers must comply with its labeling and MSDS requirements by November 25, 1985. Employers, thereafter, must meet the worker communication requirements by May 25, 1986.

The rule provides that it is intended to preempt any state law pertaining to this subject, although the OSHA administrator has indicated that OSHA would not assert preemption over any State rules until the effective date of the Federal standard (Nov. 25, 1985). Nevertheless, in the past 3 years, numerous State and local governments have enacted right-to-know laws and ordinances. These enactments can be classified as follows:

1. *Worker right-to-know* laws are designed to expand the rights created by OSHA by giving workers in other sectors access to technical information concerning the hazardous substances to which they are exposed, and by increasing the list of hazardous substances to which such access rights apply.
2. *Comprehensive community right-to-know* laws are designed to give local officials and/or residents access to technical information concerning hazardous substances at facilities within a community, without regard to the use to be made of that information.
3. *Limited community right-to-know* laws are designed to give specified local officials access to technical information concerning hazardous substances at facilities within a community, for the purpose of facilitating appropriate responses in the event of emergency and/or protecting emergency response personnel.

Such laws are likely to face a legal challenge on the grounds that right-to-know requirements have been preempted by the OSHA rule.[28] Like the OSHA rule, typical State right-to-know laws are limited in their application to a specific list of hazardous substances, rather than to hazardous substances generally. For example, the Massachusetts law[29] directs its Commissioner of Public Health to compile a substance list. The initial list included approximately 2,000 substances.

New Jersey's law[30] has been challenged, and found invalid by a U.S. District Court, in its application to the manufacturing sector, due to OSHA preemption.[31] It is still in effect for other industries, however, and requires State agencies to compile three sets of lists: a short list of "Environmental Hazardous Substances" (now approximately 154 substances); a more comprehensive list of "Workplace Hazardous Substances" subject to less thorough reporting requirements (about 800-1,000 substances); and a "Special Health Hazard" list of substances that pose special hazards because of their known carcinogenicity, mutagenicity, teratogenicity, flammability, explosiveness, corrosivity, or reactivity.

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[27] 29 CFR Sections 1910.1200.

[28] See, for example, *New Jersey Chamber of Commerce* v. *Hughey*, 12 OSHC 1121 (D.N.J., Jan. 3, 1985), which invalidates New Jersey's right-to-know law insofar as it applied to manufacturing industries.

[29] Massachusetts General Laws c 111F.

[30] Chapter 315 of the Acts of 1983.

[31] *New Jersey Chamber of Commerce* v. *Hughey*, op. cit.

The New Jersey law, as still valid, applies to research laboratories that are part of facilities engaged in:

- pipelines, transportation, communications, electric, gas, and sanitary services;
- wholesale trade, nondurable goods;
- automotive repair, services, and garages;
- miscellaneous repair services;
- health services;
- educational services; and
- museums, art galleries, botanical, and zoological services.

The law also applies to State and local governmental laboratories. By exclusion, therefore, the law does not apply to retail trades, the professions, most service industries, and R&D laboratories that are not part of a covered facility.

The Massachusetts law, as yet unchallenged and now being implemented, exempts research laboratories not involved in the production or manufacture of goods for direct commercial sale.

Comprehensive right-to-know laws, of course, are far less restrictive. Massachusetts, for example, requires that an MSDS for each substance at an installation be filed with the Department of Environmental Quality Engineering (DEQE) and, on request, with a designated municipal coordinator from the community in which the installation is located. Thereafter, any community resident who has reason to believe that a hazardous substance may be endangering public health or safety may request an investigation by the municipal coordinator. If an investigation is deemed necessary, DEQE can provide relevant MSDSs to the petitioning resident in appropriate cases. The investigation is intended to ascertain what, if any, State or local action is necessary to protect the health or safety.

The New Jersey law is even less restrictive. It requires employers to submit environmental surveys to the Department of Environmental Protection (DEP) and the health department of the county in which the facility is located, as well as pertinent parts of the survey to local fire and police departments. Any person making a written request would obtain a copy of the survey from the DEP. In addition, a list of workplace hazardous substances at each installation and the MSDS for each one were to be maintained by the Department of Health and made available on request to any person.

In the 99th Congress, a number of legislative proposals have sought to extend community right-to-know and accident control provisions. H.R. 963, introduced February 6, 1985, by Representative James Florio (D-NJ), would amend the Occupational Health and Safety Act of 1970 to permit States to adopt more stringent right-to-know provisions for access to information. The "Chemical Manufacturing Safety Act of 1985," H.R. 965, also introduced on February 6, 1985, by Representative Florio, amends the Toxic Substance Control Act to add provisions concerning a community's right to know of the risks, emergency planning, and liability for hazardous substances releases. Research laboratories and hospitals are exempt, if the substance is used under the direct supervision of a technically qualified person.

H. Con. Res. 53, introduced by Representative Bob Edgar (D-PA), is a concurrent resolution expressing the sense of the Congress that all persons have a fundamental right to know when they are exposed to hazardous substances that may be dangerous to their health. In part it declares that the Assistant Secretary for Occupational Safety and Health should immediately revise the hazard communication standards to extend right-to-know protection to employees in any service or industry that employs hazardous substances and that the Federal right-to-know standards should set only the minimum requirements that the States must follow. On March 6, 1985, Senator Alfonse D'Amato (R-NY) introduced S. 606, the "Community Right to Know Act of 1985." It provides for the annual notification to a city or county of the presence of hazardous substances in or near such city or county (within a 10-mile radius) by the owner or operator of such a facility.

On March 21, 1985, Representative Robert Wise (D-WV) introduced H.R. 1660, the "Hazardous Materials Manufacturing Safety Act of 1985." Similar to H.R. 965, the bill would amend the Toxic Substance Control Act to add provisions concerning a community's right to know of the risks, emergency planning, and liability for hazardous substances releases. And finally, H.J. Res. 225, "The Hazardous Substances 'Right-to-know' Resolution," introduced by Representative Bruce Vento (D-MN) on April 4, 1985, mirrors the H. Con. Res. 53 expression of a person's fundamental right to know when they are handling or are exposed to a hazardous substance that may threaten their health and well-being. It also declares that OSHA should immediately revise its Hazardous Communication Standard to extend "right-to-know" protection to all workers in industries and services and that the Federal standards should only be minimum requirements that the States must follow.*

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*These legislative initiatives contrast sharply with the political assumptions directing similar European efforts, where public disclosure is limited. In 1979, the European Community adopted a Directive, commonly called the Sixth Amendment, containing provisions for the testing of chemicals to be placed on the market, and for the notification to governments of the results of such tests, as well as for chemical classification, packaging, and labeling. The Sixth Amendment requires an importer or manufacturer proposing to place a new chemical on the market to submit a premarket notification to the appropriate regulatory body of the member nation where the substance is produced or imported. The notice must contain health, environmental, and physio-chemical test data on the substance, estimated volume and uses, and recommended precautions. On the basis of the data submitted, packaging and labeling requirements may be imposed. Exempted are substances subject to other regulatory programs, such as medicinal and radioactive substances, waste substances and pesticides, research substances for evaluation, and substances marketed in quantities less than 1 metric ton per year per manufacturer.

The most important European Community enactment on risk communication for the control of chemical accident hazards is the "Seveso Directive." This Directive is named for the town in Italy where explosions at a Hoffman-LaRoche plant in 1976 spewed dioxin into the community, necessitating removal and testing of its inhabitants.

Adopted in 1982, the Seveso Directive is to be fully implemented by the member nations in 1989. Under the directive, a manufacturer who conducts activities which involve one or more of 178 designated substances must provide to the competent national authority: information on the substances and the processes used, information on the installation (facility), information on possible major accident situations, new information relevant to safety and hazard assessment on a periodic basis, and special information on multiple installations close to dangerous substances.

Each member nation is required to designate a competent authority who will be responsible for receiving the information from the manufacturer, examining it, requesting additional information, developing an off-site emergency plan, organizing inspections, and determining that the manufacturer takes the most appropriate steps to prevent major accidents and limit accident consequences. The directive thus represents the most complete and integrated approach taken to date to prevent chemical accident hazards. The directive reflects European values in vesting full responsibility for public safety in public officials, in restricting the flow of risk information to protect industrial secrecy, and in affording citizens and interest groups no access to the risk communication process or to the information outputs of the process.

Chapter 6

Institutional Differences

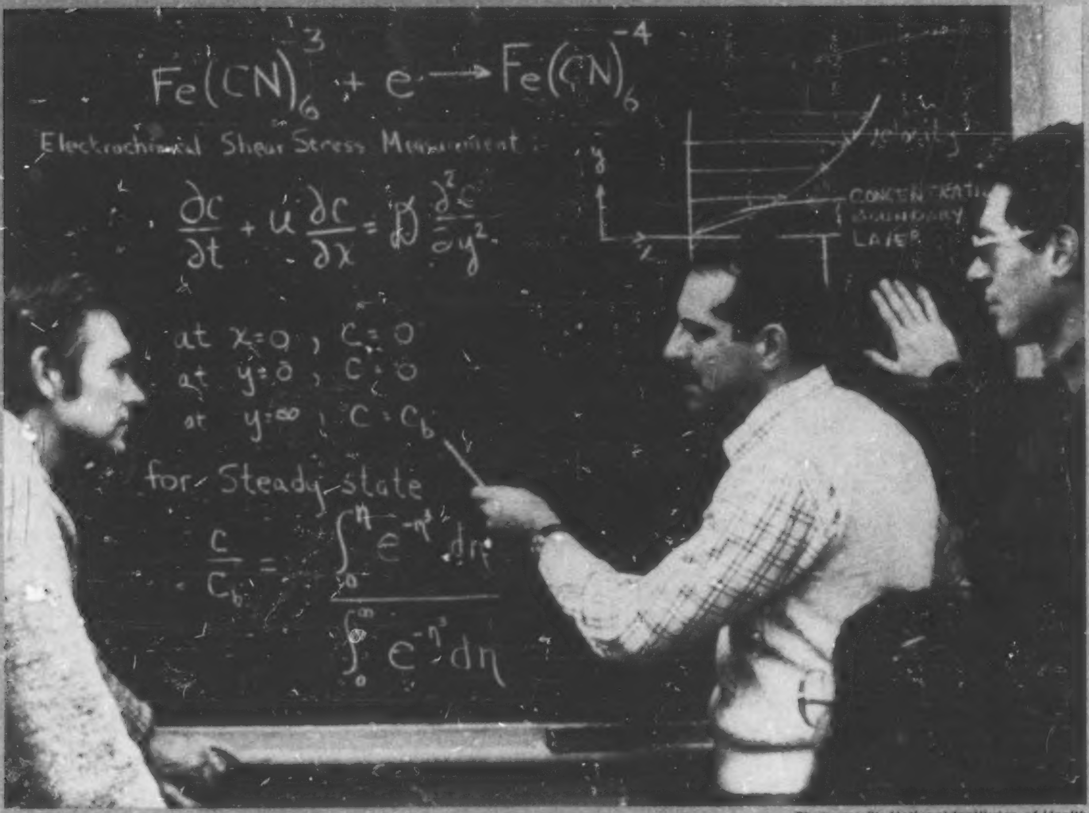
Fe(CN)6-3 + e → Fe(CN)6-4
Electrochemical Shear Stress Measurement
at x=0 , C=0
at y=0 , C=0
at y=∞ , C=Cb
for Steady state
CONCENTRATION BOUNDARY LAYER

Photo credit: National Institutes of Health

Chapter 6

Institutional Differences*

Research in the United States is performed in a number of different institutional settings—in university laboratories, in industry, in nonprofit institutions, and in government laboratories. The following profiles give examples of how some of the mechanisms described in chapter 4 apply in three different institutional settings. The profiles are based on interviews and data gathered in actual laboratories.

PROFILE OF A REPRESENTATIVE INDUSTRIAL LABORATORY

After acquisition in 1981 by a major international chemical firm, this laboratory was made part of a newly formed pharmaceutical products division. One of the largest U.S. producers of radioactive chemical compounds for life science research and radiopharmaceuticals, the pharmaceutical products division's research activities are principally aimed at new product development, at improving production efficiencies, and at developing radioisotope marking procedures for the fields of radiopharmacology, life science chemistry, and biotechnology. In addition, the division conducts research on industrial health and safety improvement techniques.

Because the laboratory's primary function is to develop and supply radioactive materials, a large portion of the research is conducted to accomplish this corporate marketing or production objective. Some research is aimed at developing a marketable pharmaceutical that will receive U.S. Food and Drug Administration (FDA) approval. Other research seeks to improve the efficiency or safety of production processes. A small portion of the division's research is conducted under contract to other industrial firms, principally to develop product-specific radioisotope marking procedures usable in their own research.

Control of the Research Agenda

Because the laboratory is a commercial facility, its research decisions are strongly influenced by such considerations as the potential profit to be earned from new product sales, or the savings to be anticipated from production efficiencies and safety improvements. Funds for research are deemed an investment and, as such, are expected to pay dividends. The laboratory's research agenda therefore depends on corporate judgments concerning the potential of research to yield dividends.

In this regard, U.S. tax policy has, in recent years, promoted research investments by granting business deductions or credits for research expenditures—for example through the Internal Revenue Code and the 1981 Economic Recovery Tax Act (see ch. 4). The effect of these provisions is to lower the effective cost of research to businesses and thereby to make the research more likely to be profitable. To the extent that tax breaks are given without regard for the content of research, all forms of research are stimulated. Virtually all of this laboratory's research falls within the categories eligible for preferential tax treatment under current law.

The most important regulatory impacts on the selection of research opportunities at this laboratory, however, are the result of policies or regulations of FDA. By specifying the evidence of safety and efficacy it will require for new drug approval, the FDA sets forth much of the research agenda for product development. The FDA regulations also control the activities that may be undertaken with investigational new drugs. By specifying the protocols to be followed for each step of such research, including toxicology and pharmacology procedures for animal testing and use of human subjects, the FDA regulations chart the course of new drug development research.

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*This chapter is based on the regulations in force in three different laboratories. Interviews and data collection were performed by Michael Baram and Raymond Miyares, Bracken & Baram, Boston, MA, under contract to the Office of Technology Assessment.

Outside of FDA requirements, the principal indirect impacts on the selection of research opportunities are higher costs resulting from compliance with health, safety, and environmental regulations. Sometimes firms engage in research in order to control and reduce these costs. For example, the high cost of hazardous and low-level radioactive waste disposal at licensed facilities stimulates interest in development, production, and recycling processes that produce less waste. At this laboratory, decisions to undertake research on ways to recover waste carbon isotopes and to reduce the curies of tritium used to produce tritium-marked products are attributable, in part, to waste disposal cost increases.

Regulations can also raise the cost of the research itself and thereby deter a firm from undertaking it. This firm, for example, has thus far declined to use P-3 level (high hazard) microorganisms in its biotechnology laboratory because of the elaborate substance approval process required by National Institutes of Health (NIH) guidelines. In interviews, company officials supplied other examples of research that they abandoned because of high regulatory compliance costs:

- The cost of establishing and maintaining a laboratory "closed box" acceptable under NIH guidelines and emission controls adequate to meet State air pollution requirements was deemed so substantial that planned research utilizing aflatoxins was abandoned.
- Similarly, the cost of obtaining an antidote for the venom of an African poisonous snake, in compliance with NIH guidelines, was considered prohibitive and research utilizing the venom was dropped.
- The Occupational Safety and Health Administration (OSHA) xylene and toluene exposure standards (to protect workers) were considered too costly to comply with in research on liquid scintillation cocktails, so that research was redirected to find scintillators with less toxic components.

Controls on the Research Process

The protocols specified in FDA regulations dictate not only the type of research necessary to support a new drug but also the research procedures to be utilized. Thus, to satisfy FDA, research must meet regulatory requirements for a "scientifically well controlled" study. Some of these steps are undertaken for no other reason than FDA requirements; in the absence of FDA regulation, the research might be designed in a more streamlined fashion.

For other types of research, regulatory requirements play a far less pervasive role. Research is designed so as to be most likely to yield the desired information. Because regulatory agencies have little interest in production efficiencies, much of the research conducted in this area, for example, is designed to suit the objectives of the researcher.

Management of Risks

Much of the division's research is undertaken by a permanent staff of scientists and technicians who expect a long-term career with the company. The long-term consequences of radiation and toxic chemical exposure are as important to them as immediate health and safety effects.

Since its acquisition by an international corporation, this laboratory has undertaken to conform its occupational and environmental health and safety practices to those of its parent company, which enjoys a national reputation for responsibility in this area. The laboratory has a safety executive committee of senior managers, with subcommittees on safety awareness, process hazards, equipment safety, chemical safety, and radiation safety. Every employee is required to attend a monthly safety seminar, and regular inspections are made, not only of the obvious hazards of chemical storage areas, radiation shielding, and electrical wiring, but also of the more mundane, such as chair hazards. On-the-job injuries, lost work time, restricted work time, medical treatment, and off-the-job injuries are reported monthly to corporate headquarters.

The laboratory workers are protected by several Federal and State regulatory programs. OSHA regulations, the most comprehensive of these, set general safety standards as well as exposure standards for toxic chemicals. Nuclear Regulatory Commission (NRC) regulations specifically govern the safety of laboratory work on radioactive materials and require dissemination of information to workers on any materials used in the laboratory and reporting of any incident involving radiation exposure. NIH guidelines govern the containment and security of micro-organisms used in biotechnology research.

The firm's preoccupation with safety also extends to environmental and community hazard concerns. The laboratory conducts annual emergency training programs for local fire officials, police, and hospitals. In addition, it complies with a panoply of Federal and State requirements for construction and operation of industrial facilities. The State plumbing code, for example, requires separate piping in the biotechnology lab for human contact and contact with organisms. The Resource Conservation and Recovery Act and corresponding State requirements, as well as NRC regulations, govern the disposal of hazardous and radioactive waste. Federal and State air quality regulations limit emission of radionuclides into the air. And, in addition, regulations under the Clean Water Act restrict the disposal of waste into publicly owned treatment facilities as well as the discharge of such waste into surface and groundwater. Under the Clean Water Act, even *de minimis* spills of hazardous substances must be reported.

Beyond these specific regulatory programs, the potential for liability under the Federal Superfund law, corresponding State laws, and the common law influences the management of laboratory risks. Such potential for liability provides an incentive for due care in the management and disposal of wastes and the emission of pollutants into the environment. However, the incentive operates further to cause the company to reduce waste generation so as to avoid strict liability even where due care has been exercised.

Restrictions on Communication of Information

As a manufacturer, the company is subject to both the OSHA hazard communication standard and the State's right-to-know law, notwithstanding that law's research laboratory component. Under both provisions, it must label—and supply its customers with Material Safety Data Sheets (MSDSs) on—all hazardous products sold. Company practice is to compile a notebook of MSDSs for all its products sold and to disseminate the same notebook to all customers with a printout listing which products they purchased during the previous 18 months.

The laboratory was in virtual compliance with the OSHA standard prior to its issuance and is encountering no significant difficulty in adapting its prior community liaison activities to the State's right-to-know requirements. For laboratory workers, it is required, under the OSHA standard, to:

- ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;
- maintain any MSDSs that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible to laboratory workers; and
- provide laboratory workers with information and training on hazardous chemicals in their work areas at the time of their initial assignments, and when a new hazard is introduced into their work area.

The State has required further that the company supply a list of the hazardous substances that it uses, and an MSDS for each one, to local officials in both the State Capital and the town in which the lab is located. Neither the OSHA nor the State list of hazardous substances, however, includes radioactive materials.

Although the laboratory often seeks to disseminate a product developed in its research laboratories, corporate policy necessarily restricts dissemination of information about its research or about research results. Such information may be legally patentable or protectable as a trade secret, and corporate policy is to control dissemination or publication of research data, especially on process refinements or improvements, unless there is a valid business reason for dissemination. On the other hand, the parent company's policy is to disseminate fully any proven safety improvements developed by corporate research laboratories.

Again, the potential for liability affects the availability of information on research. The laboratory has a "document retention program" that requires disposal of all documents not required to be retained for a business purpose or by regulation, the objective of which is to avoid a paper trail that could be used in enforcement or liability proceedings against the company. This program can be seen as a prudent response to the liberal discovery rights afforded litigants in the courts today, but it may also cause information on prior research to be lost to researchers within the company.

PROFILE OF A REPRESENTATIVE NONPROFIT INDEPENDENT LABORATORY

This cancer research center is one of several teaching hospitals affiliated with a major medical school, although its Board of Trustees is fully independent of the school. The center is involved in cancer research of virtually all types, from cell biology to clinical trials, with a special emphasis on childhood cancers. Its research divisions include specialities in: biostatistics and epidemiology; cancer control, genetics, and pharmacology; cell growth and regulation; immunogenetics; medical and pediatric oncology; medicine; and tumor immunology and virology.

The center administers an annual budget which, in 1984, exceeded $55 million. Of this amount, approximately 45 percent was for patient care and services and the remainder was for research. The center maintains a 57-bed inpatient facility and provided care through nearly 24,000 outpatient visits in 1984. Approximately 50 percent of the center's patients participate in some form of clinical study, however, and the line between research and patient care is not always precise.

Approximately 80 to 85 percent of the center's research is funded by Federal grants from NIH and the National Science Foundation (NSF). Of this amount, about 70 percent comes from the National Cancer Institute (NCI). Of the remainder, most comes from private granting organizations such as the American Cancer Society and the National Leukemia Foundation (principally for student fellowships). Approximately 5 percent of research funds come from other private sources.

The center's therapeutic research often involves highly toxic chemical agents or radiation, and, of course, the use of human subjects. The hazards of the research may be concentrated on these subjects in some circumstances, and human subjects must be informed of, and consent to, acceptance of the related risks before participating in a clinical study in the hope of achieving therapeutic benefits.

The center's research staff of 600 includes approximately 350 with doctoral degrees. Much laboratory research is conducted by technicians. Such technicians typically have a high turnover rate, so that long-term exposure to laboratory chemicals and radiation is unusual. Nevertheless, some research personnel, both professional and nonprofessional, perform research over a period of several years.

Control of the Research Agenda

The center has a fairly formal administrative hierarchy that sets the general theme of the research to be undertaken. Because the center is itself mission-oriented (i.e., devoted to cancer research), and its principal funding sources share nearly the identical research mission, the center's broad outlines of research are not generally affected by considerations of funding availability. To be sure, the work of an individual researcher or laboratory might be terminated if funding were withdrawn. Much of the research staff is dependent on continuing funding for their employment. Further, if NCI were abolished or fundamentally redirected, the center's research agenda might be substantially affected. The importance of cancer research in American public health policy, however, makes the possibility of a major redirection remote.

Indeed, it is this public policy commitment, rather than the mission of funding sources, that appears to affect the center's selection of research opportunities. For example, the center has thus far declined to undertake a large amount of epi-

Box A.—An Assessment of Regulatory Forces by Lab Directors and Research Administrators

In March 1985, OTA sent questionnaires to 32 university research administrators (deans and vice presidents) and 112 laboratory directors around the United States. The two groups were selected because of their varying roles in the university research process; administrators tend to be intimately involved in the research administration policies established and followed within the university and the lab directors are more involved with concerns linked to their particular field. The laboratory director group was selected from the Gale *1984-85 Research Centers Directory*. Out of the 7,427 entries for the United States and Canada, at least two were chosen from every State and from the disciplinary divisions according to the following proportions: agricultural and nutrition sciences, 5 percent; astronomy, 5 percent; engineering (research), 20 percent; life sciences, 20 percent; mathematics and computer sciences, 20 percent; physics, 25 percent; and social sciences, 5 percent. Laboratories of all sizes were chosen randomly within the above parameters. The response rate for this group was 23 percent.

The research administrators were chosen from the top 32 research universities in the country based on the level of Federal funding for research, according to the NSF *Academic Science R&D Funds: Fiscal Year 1980*, Surveys of Science Resources Series. Forty-four percent of the research administrators responded to the survey. The aggregate response rate was 27.7 percent.

Participants were asked to identify major regulatory forces in their research institutions, trends in regulation of research, and channels or forums for discussing solutions to potential problems. In general, there were few differences in the forces listed between the responses of the two groups.

Major Regulatory Forces.—The regulatory forces listed by the respondents can be classified into four major areas: controls on substance, whereby nonscientific forces are setting or influencing the research agenda; controls on process, whereby the nature of the research is not under consideration, but the means and methods used to accomplish the research goals are regulated; administrative constraints (including the funding process); and restrictions on dissemination of research results.

Clearly, the regulatory forces that are most keenly felt by both groups are the Federal guidelines for the protection of human participants and animals in research. But following closely in the ranking are many unintentional regulatory forces, such as environmental, health, and safety legislation intended to protect the general public; or radiation safety regulations, environmental and worker protection laws, and Good Laboratory Practice Standards intended to protect labor.

Administrative constraints were listed as a major area of concern by 37.5 percent of all respondents. Perhaps predictably, university administrators saw the financial accounting requirements as most pernicious. When the responses are disaggregated, 64 percent of the administrators v. 23 percent of the lab directors, listed financial accounting requirements as a major force.

Both groups found "social regulations" to play a major role. Social regulations include laws to encourage small business and minority business subcontracting, Fair Labor Standards, and Equal Employment Opportunity Commission and Affirmative Action requirements. Because respondents were not asked to rank their answers, it is not clear how much of a force they feel these regulations present. The frequency of responses, however, indicate that they are not as significant a force as the administrative and accounting requirements.

There was not a strong indication that either group feels that there are major regulatory forces affecting the research agenda, although a few respondents from each group indicated that national priority setting is increasingly affecting the research agenda, particularly as a result of increased defense spending and concern about industrial competitiveness. Only 17.5 percent of the respondents listed controls on dissemination of research results as a major force.

When asked whether they believed that the controls they had listed were any different from controls experienced by other universities, 86 percent of the administrators responded that they did not feel "singled out." The major regulatory forces affecting them are most likely the same for other research institutions.

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demiological research in the area of cancer prevention because of its doubts about the long-term commitment of NCI to such research. A cancer prevention epidemiological study would require a commitment to long-term funding without any important intermediate benefits to be derived from the research. National policy, in contrast, focuses on research with measurable output within a short time span, and the center has not been satisfied that funding for cancer prevention or epidemiological studies would not be terminated before usable results could be achieved.

With this exception, the principal factor governing the choice of research activities is the individual strategy of the principal investigator. Because staff investigators are selected on the basis of the congruence of their expertise and interests with the center's research mission, the focus of its effort is maintained without any formal structure to review research proposals for consistency with the center's objectives.

Virtually all of the research conducted at the center is investigator-initiated, and very little is contract work. NIH and NSF proposals—as well as others—are peer reviewed, and this review, in some instances, may tend to discourage funding of highly innovative research projects in favor of more conventional undertakings. However, the vagaries of peer review are regarded as less influential on an organization such as this center than they might be for another research facility of lesser reputation.

The impact of all types of government regulation on the selection of research opportunities is also fairly minor. The cost of compliance with regulatory requirements is incorporated into grant applications and is rarely so significant that funding is jeopardized. Moreover, the very properties that make a substance or procedure a candidate for regulation often also make it attractive as a subject for research.

Control of the Research Process

Because NIH funding is so important to the center's research, the protocols established by that agency strongly influence the conduct of that research. Moreover, NIH guidelines have become, in many instances, the industry custom for laboratory research, and thus are followed even beyond the jurisdiction of NIH. NIH has published guidelines for animal testing, for the use of human subjects, for recombinant DNA research, and for the use of investigational drugs. The latter guidelines apply when NCI provides a pharmaceutical on which research is to be conducted; if an investigational drug were applied by a private firm, the firm would have to obtain FDA approval and meet FDA requirements established for such drugs. In general, the center attempts to relieve its researchers from the nonsubstantive burdens of these guidelines and to assign to administrative staff the responsibility for paperwork and managerial burdens.

A more fundamental effect on the conduct of research is perhaps caused by the structure of the usual grant agreement. Although NIH is authorized to make research grants for up to 7 years, the typical grant is generally for 3 to 5 years and never longer. On the average, an NIH grant provides 3½ years of funding. This limit is set, not so much by policy considerations, which arguably favor longer grants that are relatively easy to administer and require burdensome administrative procedures less frequently, as by the demands of peer review. Often reviewers recommend funding for less than the total period of time requested in order to allow for thorough review at frequent intervals. A possible impact of such temporal limits, however, is to promote research protocols that permit tangible work products in shorter time periods.

A principal limitation of NIH funding is that it does not fully cover experimental patient care. This is not a reflection of any NIH judgment that it is not responsible for experimental patient care, but rather a dictate of the limitations of available funds. Third-party procedures (e.g., Medicaid and Blue Cross/Blue Shield), in contrast, do not assume responsibility for experimental clinical procedures. Thus, a gap exists, at least in theory, between NIH funding and third-party procedures. In practice, the gap is less significant than it appears, in part because the line between clinical research (nonreimbursable) and "best patient care" (reimbursable) is not precisely drawn. However, as pressure to control medical costs increases, third-party providers are likely to draw a more restrictive line of distinction and more experimental patient care may have to be funded by NIH.

Management of Risks

The center is subject to OSHA, the Environmental Protection Agency, and NRC regulations governing work place safety, environmental protection, and radiological health. The center's Division and Laboratory Chiefs are responsible for assuring compliance with such regulations by those they supervise. In addition, the center is subject to the Joint Committee on Hospital Accreditation, a hospital self-regulating organization that approves radiation, chemical, and biological safety programs. The State and city in which the laboratory is located further regulate aspects of health, safety, and environmental hazards, including fire and chemical hazards and the biohazards of recombinant DNA.

As noted, NIH guidelines govern the use of human subjects in research, and these guidelines generally require the approval of the research protocol by an Institutional Review Board and the informed consent of the human subject or legal representative. Typically, the center has found, its patients are relatively sophisticated about the nature of their disease, the hazards of research, and the potential for harm. The center is a tertiary care facility, and the majority of its patients have substantial experience with medical procedures and treatments. Therefore, the content of its informed consent form can sometimes be relatively more technical than corresponding documents at other facilities such as at a primary care hospital.

The informed consent form states the center has "no formal policy" with regard to compensation of research subjects who are injured in the course of research. In practice, medical cost incurred as a result of such injury might be paid by the third-party provider. In particular circumstances, however, the center might seek to assume or divide these costs.

Controls on Communication of Information

Because the center regards its staff to be both intelligent and well-educated, it relies on the provision of chemical and radioactive hazard information as the principal instrument for managing risk hazard. The center employs one half-time chemical safety information officer whose exclusive responsibility is to provide relevant information about substance hazards and appropriate precautions and responses, as well as to perform laboratory inspections.

The center, however, is not subject to either the OSHA hazard communication standard or the State right-to-know law. The OSHA standard, as noted, applies only to workers within the manufacturing sector. The State law exempts research laboratories not involved in the production or manufacture of goods for direct commercial sale. The regulations issued under the law require an application for an exemption to be filed by each laboratory. The center has filed such an application and, while that application is pending before the State department of public health, the center is exempt from right-to-know requirements.

A principal objective of the research conducted at the center is the dissemination of user results. Dissemination serves the interests of the center's mission by advancing the state of knowledge about cancer and also enhances the reputation and standing of the center and its staff. Therefore, the center will not accept research funding that requires secrecy. Nevertheless, some limits on dissemination are accepted. Grant agreements may specify, for example, that publication of research results might be delayed for up to 3 months in order to allow for review by the sponsor. Such limits do not generally appear in NIH or NSF grant agreements. Indeed, the policy of Federal funding organizations is to stimulate the dissemination of research results, and failure to publish may be considered negatively in evaluation of new grant proposals.

A theoretical restriction may also derive from the practice of some center staff to consult privately for industry. In such circumstances, the staff member could feel disinclined to publish results seemingly adverse to private clients. Such an impact may be completely unconscious and impossible to demonstrate, but the restriction may nevertheless operate.

PROFILE OF A REPRESENTATIVE UNIVERSITY LABORATORY

The Department of Chemical Engineering at this major research university engages in a range of research projects and activities in support of the academic development and advancement of its students and faculty. Although much of this research is funded from outside sources, the department does not principally engage in client services, but rather seeks grant support for research into chemical transformation and separation processes, and energy intensive functions of relevance to the interests of its members. The principal areas of interest include coal conversion, synfuels developments, utilization of micro-organisms in chemical processes, and polymer production. Approximately 30 to 40 percent of the department's research funds come from private sources (e.g., one international corporation contributes $1 million annually); the remainder are Federal grants, principally from the departments of Energy and Defense (DOE and DOD) and NSF.

Much of the department's research is conducted at a very small scale, utilizing small quantities (often less than a gram) of chemicals in any particular step. However, a great variety of chemicals are involved in the department's research programs so that the cumulative hazard of the research is highly variable. An exception to this pattern of low volume and high variety is in the area of combustion engineering, in which substantial volumes of petroleum products are burned in the course of research.

In many instances, laboratory research is conducted by students rather than by staff technicians. Because the turnover rate for both students and technicians is fairly high, most of the people who work in the department's labs are not subject to long-term exposure to laboratory chemicals. The students, however, may be more vulnerable to risks because they are relatively naive and untrained in laboratory safety procedures and may be somewhat less cognizant than career workers of the hazards of their research. This situation influences the amount and type of safety measures taken by the university.

Controls on the Research Agenda

Because the university lacks the formal hierarchical administrative structure of a commercial enterprise, decisions to undertake research are relatively individual and idiosyncratic, rather than directed by an overall institutional strategy. Clearly, the availability of funding affects the research agenda, but this financial incentive differs from that of an industrial laboratory, which must make its research choices based, in part, on an estimate of the market impact of the anticipated results. Further, because of its stature in academic circles, the department carries considerable weight in negotiations with potential sponsors over the content and conduct of its research activities.

This is not to say that research sponsors have no influence over the manner in which their funds are utilized. Many Federal sponsors and some foundations, as well as virtually all commercial sponsors, are mission-oriented. Such sponsors make their grant awards based on whether they perceive the research to promote their particular mission objectives. Approximately 75 to 80 percent of the department's research funds come from such mission-oriented sponsors, which include DOD and DOE, the petroleum and chemical manufacturing industries, integrated circuit manufacturers, and pharmaceutical companies. The remainder comes from sponsors seeking to support "basic" research—some DOE programs, NSF, and private foundations.

The impact of regulation on the selection of research opportunities is, by contrast, fairly minor compared to the academic interests of the faculty and the mission objectives of sponsors. Because the department's research seeks to be at the cutting edge, regulation addressing the specific substances or processes under investigation may not yet have been developed. The cost of complying with health, safety, and environmental regulations is rarely so significant that research is foreclosed. To the extent that such regulation raises the cost of certain lines of inquiry and thus may divert attention to other research activities, this effect is countered somewhat by intellectual interest in studying "problem" chemicals and process—those that may be the subject of extensive regulatory attention.

Because combustion engineering research has different characteristics from other research conducted in the department, the effect of regulation of this research is also somewhat different. In particular, research into the emissions produced by combustion processes requires the use of substantial volumes of fuel. Often, from a purely research perspective the fuel of choice would be benzene, but benzene is the subject of such intense regulatory scrutiny that researchers are reluctant to use it if a relatively less problematic alternative such as toluene is available. This reluctance stems both from current regulatory activities (principally by OSHA) and from the concern that department researchers share with regulators over the hazards of the substance.

A similar effect may be discerned with respect to the use of radioisotopes in research. Because of the regulatory burden of becoming licensed to handle radioisotopes and the cost of their disposal under NRC regulations, their use is discouraged if alternative research procedures are available. Again, the effect may be to skew the allocation of research resources.

Controls on the Research Process

Most research grant agreements specify how research activities are to be conducted; but the level of specification varies considerably with the sponsor. Sponsors of basic research typically require a proposal that sets forth the research protocol in sufficient detail to allow reviewers to judge the technical adequacy of the research. Such protocols are often thereafter incorporated by reference into grant agreements, but most sponsors do little supervision or monitoring of performance under these agreements.

Industrial sponsors may provide "foundation" grants intended to support the department's general research activities, rather than any particular project. Such broad grants are less likely to constrain the specific conduct of research. When industrial sponsors underwrite a particular research project, however, the grant agreement may include specification of the research protocol. Surveillance of the department research, however, is somewhat more extensive in that reporting requirements are more often imposed and site visits more frequent.

Mission-oriented Federal agencies, such as DOD and DOE, tend to specify research protocols in the greatest detail. Such protocols are drafted, not only to assure the technical adequacy of the research, but also to assure that research results will be usable by the sponsor in achieving its objectives. Commonly specified details include performance requirements, cost allocations, equipment, milestones, and personnel. This greater specification is typically accompanied by greater supervision and monitoring of the research. The Department of Defense is especially strict in its surveillance of the research it sponsors; however, this university does not automatically comply with DOD's (or any other sponsor's) requests for secrecy in the conduct of research. Because it is an academic institution principally devoted to education, the university laboratories are widely open to students and faculty. Classified or weapons-related research is deemed an inappropriate activity for an academic institution, although it may be conducted at university affiliated laboratories off campus.

Management of Risks

The university maintains a Safety Officer and an Office of Environmental Medical Services which are intended as a resource to consult in the design of laboratory risk management activities and to facilitate compliance with environmental, health, and safety regulations. In addition, the university faculty maintains nine standing committees that develop risk management procedures to be used in research:

- Council on Environmental Health and Safety,
- Committee on Assessment of Biohazards,

- Committee on Radiation Protection,
- Committee on Safety,
- Committee on Animal Care,
- Committee on the Use of Humans as Experimental Subjects,
- Committee on Toxic Chemicals,
- Committee on Radiation Exposure to Human Subjects, and
- Committee on Reactor Safeguards.

The university will not approve a grant agreement or research contract that has not been approved by the committee having jurisdiction over such research.

In general, the safety practices established by these offices and committees are equivalent to, or more stringent than, corresponding regulatory requirements. Often, the faculty have been involved in the development of Federal regulatory requirements and their influence is reflected in the requirements adopted. Nevertheless, researchers are always alert to proposals for regulatory requirements that specify unachievable standards or unworkable administrative burdens. For example, a new State plumbing code originally would have required that *no* micro-organisms be disposed of in the wastewater of laboratories where biotechnological research was being conducted, even though there are safe and acceptable levels of micro-organisms commonly allowable in wastewater generated by nonresearch facilities.

The department's laboratories are subject to a range of environmental and occupational safety and health requirements that typically include: 1) safety or health standards for emissions of, or exposure to, a particular substance; and 2) documentation of compliance with such standards. Many of these regulations specify the chemical substance as the unit of regulatory attention, and the paperwork burden of reporting requirements varies with the number of chemical substances used in research. Because department research typically utilizes tiny quantities of a multitude of chemical substances, the paperwork burden is substantial even though the exposure and emission standards may be fairly easy to achieve.

An example is provided by the regulations under the Resource Conservation and Recovery Act (RCRA) for hazardous waste disposal. These regulations essentially prohibit the disposal of substances on the hazardous waste list by conventional means (emission standard=0) and instead require that licensed hazardous waste transporters and disposal facilities be utilized. The regulations further specify the packaging and paperwork requirements to be followed in the disposal of hazardous wastes. At this university, hazardous waste from chemical engineering laboratories is sent to the safety office where such waste is collected from all parts of the university. Much of this waste is unique and packaged in tiny vials. Traditional practice has been to combine vials of compatible wastes in "laboratory packs"—conventional drums lined with absorbent material—before shipping them off for disposal. The regulatory manifest, however, requires that the contents of each vial in the lab pack be separately identified, and monthly and annual generator reports required under RCRA also must include information on each vial. Because the waste in each vial may be unique, the information necessary to complete the manifest may not be routinely available, and the safety officer may encounter some difficulty in preparing the waste for shipment. A barrel of industrial waste, in contrast, is likely to contain only one waste type that is routinely generated. The paperwork burden for this barrel is correspondingly light: Only one substance needs to be identified on the manifest and the information to be provided is the same day after day.

Similarly, the State's Clean Air regulations require an individual permit for each vent through which air pollution emissions are made. The university has approximately 20 such permits for the Department of Chemical Engineering and each one is supposed to include a specification of the substances being emitted as well as the technology being employed to reduce those emissions. Because laboratory work varies over time, however, any specification of substances in the permit is necessarily uncertain. Moreover, if an honest effort is made to specify all of the substances likely to be utilized in the laboratory, the permit application must then demonstrate that the technology is in place to reduce emissions of the full list of substances. Nothing in this State law exempts from the permit requirement substances that are being emitted in *de minimis* quantities.

Essentially, these two environmental regulatory programs were devised with a different model of facility in mind; it is increasingly apparent that regulations devised for industrial facilities may be poorly suited for application to research laboratories. RCRA regulations do include a partial exemption for small quantity generators, but this is of no use to the university, which clearly does not qualify as a small generator because of its substantial total volume of waste. If paperwork burdens are to be more closely related to the hazards of the regulated activity, new efforts are required to tailor regulatory requirements to the type of enterprises being regulated.

One such effort is suggested by the statement of projected rulemaking issued by OSHA on April 29, 1985, concerning health hazards of chemicals in laboratories. In that statement, OSHA observed:

> Existing OSHA standards are designed to protect employees who are engaged in work involving exposure to only a few toxic chemicals during relatively standardized, continuous or repetitive processes. In contrast, laboratory workers are exposed to a multitude of toxic substances under frequently changing or unpredictable conditions. OSHA will examine whether prudent work practices and protective equipment, chosen for the specific facility and task, are more effective, feasible and economical for laboratory work than adhering to OSHA's current substance specific exposure standards.

Such a proposal appears to be better suited to achievement of the goals of environmental, health, and safety regulations than the traditional approaches. The effect of traditional regulations, in many instances, is to consume the time of safety personnel in the documentation of compliance rather than to stimulate such people to devote their time to analyzing problems for which routinized solutions are not readily achievable.

Restrictions on Communication of Information

It is the formal written policy of the university that people who may be exposed to hazards should be informed about the nature of these hazards and how to protect themselves and others who also may be exposed. Faculty, administration, and research supervisory personnel are responsible for promoting safe practices and for informing individuals working in laboratories about safety in connection with the work being conducted.

This policy derives from the university's assessment of its own responsibility under ethical and general liability principles rather than from a particular hazard disclosure regulation or statutory requirement. For example, the OSHA hazard communication standard applies only to workers within the manufacturing sector. Therefore, no university laboratory is subject to its requirements.

Similarly, the State right-to-know law exempts research laboratories not involved in the production or manufacture of goods for direct commercial sale. The regulations issued under the law require an application for exemption to be filed by each laboratory. The Department of Chemical Engineering has filed such an application for its laboratories, which is presently pending before the State Department of Public Health (DPH). Under the regulation, the department is exempt until DPH rules on the application.

Nevertheless, the State law does affect university operations in other ways. A number of vendors have terminated all business in the State in response to the law, so that alternative vendors have had to be found in some instances. In addition, MSDSs being supplied with chemical products sometimes appear to have been prepared by lawyers to achieve minimal compliance with regulatory standards and to provide the least incriminating information possible, rather than by persons desirous of promoting proper management of substance hazards. For this reason, when the university is establishing safety procedures, it frequently uses MSDSs prepared by an independent service, rather than those supplied by manufacturers.

Clearly, a principal objective of academic research is publication and dissemination of research results both to advance the state of knowledge in the research field and to advance the reputation and study of the department and its faculty. As noted, therefore, the university will not approve funding arrangements that require secrecy in the conduct of research and the dissemination of results.

Nevertheless, some limits on dissemination are common. Grant agreements may specify, for example, that publication of research results must await a release by the sponsor. In some circumstances—for example, where proprietary information has been licensed to the department for the conduct of research—the sponsor may require that articles proposed for publication be submitted for review in advance to assure that inappropriate disclosures of patentable material or trade secrets are not made.

The department's agreement with the corporation cited above, for example, illustrates how these provisions operate. Under that agreement, the university will hold the patent on any discovery made in the course of the research funded by the corporation, subject to the corporation's royalty-free license. If the university does not develop its patent, then the rights will revert to the corporation. The corporation is also given 10 days to review articles proposed for publication and to make any objections. Of course, the principal restraint on publication under this arrangement may not be the final restrictions of the grant agreement but the desire to maintain a harmonious relationship with a major source of research funding.

Chapter 7

Community Control of Research: Two Case Studies

Photo credit: National Institutes of Health

Chapter 7

Community Control of Research: Two Case Studies*

This chapter describes two cases involving precedent-setting interventions into scientific inquiry by a local government in Massachusetts. The first describes the city's two-phase regulation of recombinant DNA molecule technology—in 1977, passage of the country's first law regulating rDNA research, and in 1981, a revised law, enacted in response to research and development (R&D) activities of newly established biotechnology firms. The second case describes the city's efforts to proscribe the handling and testing of certain chemical warfare agents by a consulting firm under contract with the Department of Defense (DOD). The public controversy over the second case was kindled in October 1983 and has been the subject of litigation since March 1984 when the city promulgated its first regulation.

The case studies that follow describe the events leading up to the respective regulations, discuss the possible national impacts of these types of cases, and survey the arguments presented in favor of and opposed to local regulation of research. The report also examines the general policy implications of these cases on the issue of freedom and accountability in the conduct of scientific research.

RESEARCH INVOLVING RECOMBINANT DNA MOLECULES

The controversy in Cambridge, Massachusetts, over research involving the use of recombinant DNA molecules began in Spring 1976. At that time, the administration of Harvard University was considering a proposal for the renovation of one of its biological laboratories. The purpose of the renovation was to construct a facility that would conform to requirements of the National Institutes of Health (NIH) for performing certain classes of rDNA experiments, designated at the time as "moderate risk." NIH was also in the process of issuing guidelines that defined six classes of gene-splicing experiments: research exempted under the guidelines; P-1; P-2; P-3; P-4; and research prohibited under the guidelines. The planned Harvard laboratory was expected to meet the performance and physical containment specifications of a P-3 facility, designed to provide a protective barrier against the release of experimental organisms. A laboratory of this type required several hundred thousand dollars in equipment and special construction techniques.

When plans for the $380,000 research laboratory were being discussed by the university administration, several Harvard scientists questioned having an rDNA facility in a densely populated area close to other research and teaching activities. The issue was taken up by Harvard's university-wide Committee on Research Policy. The Committee responded by holding an open meeting for the Harvard community which was also attended by a member of the Cambridge city council and a reporter from a weekly newspaper, *The Boston Phoenix*. A news story on the meeting, "Biohazards at Harvard"—the first media report of the controversy surrounding the new laboratory—appeared in the *Phoenix* on June 8, 1976. [1] Troubled by the story, Cambridge Mayor Alfred Vellucci decided to hold hearings on rDNA research at Harvard. Mayor Vellucci was supported and advised by several scientists in the city, including some of Harvard's own faculty.[2] When the city council held hearings on June 23 and July 7, 1976, scientists and physicians affiliated with Boston-area universities and hospitals were among those who testified. Academic and biomedical research centers outside of Cambridge, contemplating rDNA research at the P-3 level, were concerned that the imposition of a city-wide ban on certain rDNA experiments would eventually affect their own institutions.

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*This chapter was prepared by OTA staff, based largely on work performed under contract for OTA by Sheldon Krimsky and on reviewer comments thereon. Dr. Krimsky is Associate Professor in Urban and Environmental Policy, Tufts University, and in 1984 was appointed Chairman of the Cambridge Scientific Advisory Committee that played a major role in the Arthur D. Little controversy detailed in this chapter. Professor Krimsky's contract report was reviewed by numerous experts, both within and outside of OTA, including Arthur D. Little, Inc., and other participants in the controversy.

[1] Charles Gottlieb and Ross Jerome, "Biohazards at Harvard," *Boston Phoenix*, June 8, 1976.

Harvard's Committee on Research Policy agreed unanimously that the research should proceed despite its potential hazards. According to the Committee, the new facility provided a sufficient margin of safety. Harvard set up a parallel review committee comprised exclusively of scientists. Known by the name of its chairman, the Branton Committee also issued a favorable response to the proposed rDNA facility. On June 14, 1976, a week prior to the first Cambridge hearing, the Harvard Corporation authorized construction of the P-3 laboratory.[3]

Subsequent to the public hearings, the city council, frustrated by the technical complexity of the issues and perplexed by the polarization of viewpoints, voted on the recommendation of one of its members to establish the Cambridge Experimentation Review Board (CERB). The city council order contained no specifications about the composition of the citizen board, leaving the appointments to the discretion of the city manager. The city council also requested that Harvard and the Massachusetts Institute of Technology (MIT) accept a 3-month, good-faith moratorium on any P-3 level rDNA research. Both universities accepted the moratorium, thus giving the newly established review board an opportunity to evaluate the risks. Since the new laboratory was expected to be completed by the spring of 1977, the city's moratorium on research did not postpone any work. However, Harvard proceeded with the laboratory's construction without assurances that an occupancy permit would be issued.

Members of CERB were appointed by the city manager in late August 1976. The manager consciously avoided the appointment of any biologists to the nine-member committee on the grounds that they were already divided on the question. (Initially appointed as a full member, the Commissioner of Health and Hospitals subsequently became ex officio.)

CERB met over a period of 4 months between September and December 1976. Harvard and MIT agreed to a 3-month extension to the good-faith moratorium on P-3 experiments otherwise scheduled to elapse in September. The citizens' committee issued its report to the city manager and the Commissioner of Health and Hospitals in January 1977. The report stated that P-3 rDNA research may be permitted on the stipulation that additional safeguards be added to the requirements of the NIH guidelines. CERB also recommended passage of a new ordinance that included the creation of a Cambridge Biohazards Committee (CBC) to oversee all rDNA research in the city. The committee's recommendations were enacted into law on February 7, 1977. The law was not subjected to legal challenge by any of the affected parties. Overall, public reaction to the outcome was favorable and controversy subsided quickly.

A second debate over rDNA activities erupted in Cambridge during 1980. This time the issue was over R&D activities in genetics. Biogen, a newly formed Swiss biotechnology firm, seeking its commercial and management headquarters in the United States, chose a site in an area of Cambridge zoned for manufacturing and light industry. Undaunted by the city's reaction to rDNA experiments 4 years earlier, Biogen officials notified the city manager and the health commissioner of the firm's interest in selecting a site and its willingness to conform to all Federal and local regulations.

CBC called a public hearing on October 28, 1980. Unlike the first rDNA debate, public opposition was mild. No biologists testified against siting the new biotechnology facility or spoke in support of additional local controls. Furthermore, beyond those employed by Biogen, Boston-area scientists were not present at the hearing. Public reaction centered around the release of genetically modified biological agents into the air and water, particularly when cultures of rDNA molecules were prepared in large scale.

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[2] For a detailed account of Cambridge, MA's involvement in the rDNA controversy, see ch. 22, Sheldon Krimsky, "Local Initiatives for Regulation," *Genetic Alchemy: The Social History of the Recombinant DNA Controversy* (Cambridge, MA: The MIT Press, 1982).

[3] Marc M. Sadowsky, "Rosovsky Approves DNA Research Lab," *Harvard Crimson,* June 15, 1976. Also, Richard Knox, "Harvard and Genetics Controversy," *Boston Globe,* June 22, 1976.

In response to public anxieties over commercial gene splicing, the city manager once again called on the Cambridge Experimentation Review Board to respond. Since CBC was responsible for implementing the rDNA ordinance, CERB considered it wise to involve this body in any decisions on revising the law. Thus, CERB chose to hold its hearings in collaboration with CBC. The joint committee developed a consultative relationship with representatives of Biogen, Harvard, and MIT. After several months of hearings and deliberations, the CERB-CBC review panel issued recommendations emphasizing safeguards against the promiscuous release of genetically modified organisms and, to a somewhat lesser degree, against occupational hazards. The Cambridge city council voted the recommendations into law on April 23, 1981. In contrast to the extensive publicity surrounding the passage of the first rDNA law, this new enactment was accompanied by little public discussion, and was only mildly acknowledged by the national media.

The new law established a permit system for all institutions intending to use recombinant DNA molecule technology. The ordinance distinguishes between small scale and large scale permits, the latter being required for cultures of genetically modified organisms in volumes greater than 10 liters. The deliberate release into the sewers, drains, or the air of any organism containing rDNA molecules is prohibited. For fermentation processes, the law also requires effective sterilization of spent organisms before they are released into the waste stream.[4]

During the second rDNA debate, the city convened a citizen review process while Biogen was in the planning stages of siting and constructing its new facility. None of the firm's research was held up as a consequence of the city's deliberations. Similarly, Harvard's P-3 laboratory was scheduled for completion in the spring of 1977, several months after the city's moratorium on P-3 experiments was terminated. Neither of the two Cambridge rDNA laws was subjected to a legal challenge. The universities considered that option but favored a negotiated settlement that avoided litigation. The 1981 Cambridge rDNA law is still in effect and is administered by the Commissioner of Health and Hospitals, who currently heads the Cambridge Biohazards Committee.

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[4] A brief history of the passage of rDNA legislation in nine cities and towns (including Cambridge, MA) and two States is presented in Sheldon Krimsky, et al., *Municipal and State Recombinant DNA Laws* (Medford, MA: Tufts University, June 1982).

TESTING CHEMICAL WARFARE AGENTS

The second case centers around Arthur D. Little, Inc. (ADL), a multi-faceted management and technology consulting firm with its world headquarters in Cambridge, Massachusetts. The firm, which has been operating in Cambridge since the early part of the century, has offices in Europe, Canada, and South America, and a work force of 2,500.

Around June 1982, ADL decided to renovate an existing chemical laboratory with state-of-the-art safety features that would enable the firm to take on work with highly toxic chemicals. The renovated laboratory was designed to meet the specifications of DOD for working with "chemical surety materials,"—chemical warfare agents—consisting mainly of nerve and blister agents.

The company's investment in the laboratory exceeded $750,000. The Philip L. Levins Laboratory was planned to occupy 1,300 square feet in ADL's Acorn Park, a 40-acre complex located at the northern boundary of Cambridge, near the adjoining towns of Arlington and Belmont. Because of the extensive renovation required, ADL applied for and was issued a building permit on December 10, 1982. Approximately a month later, ADL personnel met with the Cambridge city manager, the fire chief, and officials of the police department to inform them about the new testing facility. Notification of the police was in conformity with DOD stipulations; surface shipments of the chemical nerve and blister agents require a police escort. ADL disclosed the general nature of the facility and indicated that, among its functions, it would be used for testing chemical agents supplied by the army. According to an official of ADL, the company was not requested to provide "specific names and toxicities of the materials it was planning to test in the new laboratory."[5]

ADL requested that city officials keep confidential the location of the laboratory and the type of work to be undertaken there. Public safety considerations were given by the firm as the reason it requested nondisclosure. The firm maintained that its policy of confidentiality would reduce the chances that the laboratory would be a target for vandalism or terrorism. The city manager, police, and fire chiefs complied with the request. ADL filed for an occupancy permit on May 18, 1983. The certificate of occupancy was issued on May 25. The laboratory was approved for operation by DOD on September 19, 1983.

Responding to the cooperative arrangement that existed between the fire departments of Cambridge and its neighboring towns, ADL also contacted officials of Arlington and Belmont in September 1983 to inform them of the new facility. At a meeting with Arlington's town manager, officials of the police and fire department, and the town's civil defense officer, ADL continued its policy of requesting confidentiality about the nature of its facility.

Arlington's town manager, however, informed ADL that he planned to introduce the issue of the laboratory at the upcoming meeting of the town selectmen. On that same day, October 14, 1983, ADL issued a press release announcing the establishment of a laboratory to be used for "advanced chemical analysis of toxic and hazardous chemicals so as to develop improved methods for detecting, identifying, and detoxifying such materials and new means of protecting people from them." The news release omitted any mention of chemical nerve or blister agents. On October 20, 1983, the story of the laboratory was reported in the *Arlington Advocate* and the *Boston Globe*. The *Globe* speculated that chemical warfare agents may be among the agents handled at the facility. On October 17 and 24, 1983, respectively, the Arlington selectmen and the Cambridge city council held public meetings at which the ADL matter was discussed.

At the October 24 Cambridge council meeting, the nature of the chemical warfare agents supplied to ADL under DOD contract was disclosed by company officials. By that time, the company had begun work on the DOD contract. The council also heard residents of the North Cambridge community voice a strong protest against ADL's testing of chemical nerve and blister agents adjacent to a densely populated area. In response to public concerns, at the same meeting the city council voted to establish a "citizens' scientific advisory board" to review the risks associated with the ADL laboratory. Individual councillors requested that ADL accept a moratorium on its tests of chemical warfare agents until the city completed its risk assessment. ADL, having to contend with its DOD contract requirements, did not accept a moratorium.

By early winter, the Scientific Advisory Committee (SAC) had still not been appointed, although responsibility for implementing the orders passed by the city council had passed to the city manager. Long delays between council orders and their implementation are not unusual in Cambridge. As the city's principal fiscal agent, the manager must consider the financial impacts of council orders and the practical consequences of its policies. In this instance, however, the hiatus between the time the SAC was created by the council and the time its members were appointed is indicative of the city manager's hope that the controversy could be resolved quickly. In late winter, however, the conflict intensified when the Cambridge Commissioner of Health and Hospitals issued an emergency regulation (March 13, 1984) that prohibited "testing, storage, transportation and disposal of five specified nerve and blister agents within Cambridge, until SAC and an independent hazard assessment has been completed and these recommendations have been reviewed by the Commissioner's office."[6]

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[5] Reid Weedon, Vice President of Arthur D. Little (ADL), comments made on Mar. 7, 1985, during a community debate between ADL and the North Cambridge Toxic Alert.

Three days later, ADL received a temporary restraining order against enforcement of the regulation from a Massachusetts superior court judge. On March 27, 1984, the temporary restraining order was converted into a preliminary injunction. The injunction against enforcement of the city regulation remained in effect until February 27, 1985, after a decision was issued by the Superior Court.

The city manager appointed the membership to the Cambridge SAC on March 26, 1984. Following established tradition, the manager accepted recommendations from the council. The committee was comprised of 16 members, including scientists, individuals in the fields of public and occupational health, and residents from North Cambridge.

SAC completed its inquiry and issued a report in September 1984. The cornerstone of its decision was a series of worst-case scenarios in which different volumes of nerve agent are hypothetically released into the environment. The analytical calculations for the worst-case scenarios were developed by a risk assessment consultant hired by the city. Building on those calculations, SAC concluded:

> . . . the benefits of research with these chemicals do not justify lethal risks to the general public. For this reason, the SAC believed that storage and testing of these chemical warfare agents within the densely populated city of Cambridge in the quantities and concentrations used by ADL is inappropriate.

The majority of the SAC members judged the risks associated with any such work to be unacceptable.[7]

On receipt of the SAC report, the Commissioner of Health and Hospitals made his interim order—prohibiting any person from testing and handling three nerve agents and two blister agents—into a permanent regulation on September 18, 1984. Hearings before the Massachusetts Superior Court resumed. The judge severed the issues into the questions of Federal supremacy and the reasonableness of the Cambridge order. On December 14, 1984, the Court ruled in favor of the city on the supremacy issue. The decision on whether the Cambridge regulation was reasonable or not and whether it conformed to State law was rendered on February 26, 1985. Once again the ruling favored the city. On the following day, the Superior Court judge proclaimed the September 1985 order of the city "valid and enforceable." The injunction, which had been in effect for 11 months, was removed by the court order.

ADL appealed the case to the Massachusetts Appeals Court on March 12, 1984. The court gave ADL immediate relief by reinstating the injunction against the order, pending the outcome of the appeal. In response, the city petitioned the Supreme Judicial Court (SJC) of the State and asked that it take the case over from the Appeals Court. The SJC agreed and heard the case on April 4, 1985. In a four to one decision issued on August 1, 1985, the SJC upheld the Cambridge regulation banning the testing, storage, transportation, and disposal within the city of the five chemical warfare agents.

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[6] Melvin Chalfen, Commissioner of Health and Hospitals, City of Cambridge, "Order on the Testing, Storage and Transportation of Chemical Nerve and Blister Agents," Mar. 13, 1984.

[7] Scientific Advisory Committee for the City of Cambridge, *Report to the City Manager on the Use of Chemical Warfare Agents at Arthur D. Little's Levins Laboratory* (Cambridge, MA: September 1984).

COMPARISON OF THE CASES

Origins of Local Regulations

The city's involvement in both rDNA research and chemical weapons testing started with citizen concerns over the research slated for a renovated laboratory facility. Harvard's P-3 laboratory, designed to conform to NIH specifications for working with rDNA molecules, was in its planning stages when the city council learned of its prospective use. In contrast, Arthur D. Little's testing laboratory for chemical toxins was completed and set for operation by the time its use became known to the Cambridge citizens. In both instances, existing facilities owned by the respective institutions were significantly renovated. Building permits were obtained and several hundred thousand dollars in renovation costs were allocated. The planned P-3 laboratory was reported in the media after information was obtained at a university hearing attended by several outsiders. Harvard neither attempted to keep the laboratory's presence confidential nor sought to inform city officials and the public of its intentions to construct the facility. Funding for the renovated moderate containment P-3 laboratory and for the research for which it was designed came from science funding agencies of the Federal Government.

ADL's Levins Laboratory was paid for entirely out of company funds. The laboratory was planned specifically for the testing of toxic substances. It was anticipated that one major source of funding for recouping the investment in the laboratory was DOD. Other potential clients were Federal and State environmental agencies and those segments of the private sector that, increasingly, have become responsible for the control of toxic substances. ADL sought to have the laboratory's purpose and function known only to a select number of local officials in Cambridge, Arlington, and Belmont, Massachusetts. Public safety was the company's reason for nondisclosure of the laboratory's purpose to the general public. ADL's efforts to preserve the confidentiality of the lab and the chemical warfare agents it was testing was thwarted when a local official from the neighboring town of Arlington, informed about the facility, filed a report with the town selectmen.

Types of Local Interventions

When the Cambridge city council learned of Harvard's plans for a new laboratory, it requested both Harvard and MIT to accept a good-faith moratorium on rDNA experiments classified as P-3 or greater under the 1976 NIH guidelines, until CERB issued its recommendations. Harvard and MIT complied. No other intervention was taken by the city until the release of CERB's report.

In contrast, ADL was unwilling to accept a general moratorium on its testing of chemical nerve and blister agents pending investigation by a citizens' committee. However, on February 16, 1984 ADL did agree to a 30-day moratorium on performing any work on new contracts involving chemical warfare agents.

In neither of the two cases did the city attempt to withhold building permits or change the zoning regulations. ADL obtained its building permit in December 1983, long before the city council became involved in the issue. Neither of the voluntary moratoria affected any ongoing research projects. The ADL voluntary moratorium was short-lived and probably not disruptive. The rDNA moratorium was targeted to research that awaited completion of the new laboratory. There were several months between the end of the rDNA moratorium (January 1977) and the opening of the P-3 facility at Harvard (spring 1977).

In response to ADL's unwillingness to accept a general testing moratorium, an action that might have threatened its contract with DOD, the city council urged the Commissioner of Health and Hospitals to act. After several months of discussion and consultation, the commissioner issued an interim public health order that prohibited the testing of five chemical warfare agents. A court injunction kept the order from being enforced during the entire period of litigation. As of the writing of this report, the commissioner's order was the sole nature of the city's intervention into ADL's testing program. SAC did recommend an ordinance that, if passed, potentially could affect research at universities and other R&D firms. To date, the proposed supertoxin ordinance has not been acted on by the city.

One month after CERB issued its report on rDNA research, the city council passed an ordinance incorporating the principal elements of the recommendations. The rDNA law, amended in 1981, requires that all individuals or institutions undertaking experiments involving the production of recombinant DNA molecules must be licensed. Except for minor differences, the requirements for research are ostensibly equivalent to the guidelines issued and periodically amended by

NIH. The law sets additional requirements for a large scale permit for which there is no counterpart in the NIH guidelines.

In conclusion, the Cambridge rDNA ordinance followed the general framework of the Federal NIH guidelines. It permitted academic and commercial research to continue while incorporating additional safeguards. The city's intervention in the testing of chemical warfare agents involved a specific, local prohibition against the use of five chemicals. This was the first stage in a long-term plan supported by some city officials to regulate all highly toxic chemical agents in research and commerce. In May 1984, Health Commissioner Murray Chalfen issued a report that included a proposed ordinance on toxic chemicals and hazardous materials. The proposal, along with the SAC's recommendations, is currently under review by the city.

Stage of the Scientific Enterprise Affected

The first rDNA ordinance in Cambridge had its direct impact on university research, particularly the field of molecular genetics. The regulatory intervention was directed at a specific technique of scientific inquiry, namely, plasmid-mediated gene transfer, which is of fundamental significance to genetics research. Any scientific discipline that planned to use the technique was ipso facto under local regulation, however.

The revised rDNA law of 1981 was a direct response to the emergence of commercial biotechnology. Its principal effect was on R&D applications of gene splicing. Special attention was given to large volumes of genetically modified organisms. The utilization of large cultures represents a stage beyond basic science. Organisms genetically modified to produce a desired product are tested in pilot plant bioreactors with capacities of a hundred to several hundred liters, a stage in product development prior to manufacturing and production. The Cambridge law sets environmental and occupational safety requirements specifically for large cultures of rDNA-generated organisms.

ADL contracted with DOD to develop detection kits for nerve agents, to study the means by which fabrics may be made impermeable to them, and to investigate methods of detoxification. The firm's R&D work incorporated the expertise of analytical chemists, product development chemists, and electronics specialists. The order issued by the city on chemical warfare agents was not targeted to a particular research technique or methodology, as in the rDNA case; instead, it prohibited the use of five substances cited in an ADL-DOD contract. The regulation was, therefore, directed at the application of science and technology for solving targeted problems. In distinction to the rDNA case, ADL's research was not designed to generate new science. The purpose of the research was to supply the army with new information on the handling, detection, and detoxification of chemical warfare agents.

Social Risk Assessment

The two cases illustrate different approaches to social risk assessment. This is particularly evident in the composition, goals, and functions of the two citizens' committees. CERB was a committee comprised of nonexperts in the subject matter under consideration, namely molecular genetics. Out of eight members, the one who came closest in expertise to the field was a physician, board-certified in infectious diseases. The membership of the committee was chosen to reflect racial, ethnic, and neighborhood diversity. It was divided equally between men and women. In an internal memo, one member likened CERB's function to that of a jury in a legal proceeding.[8] This memo clarified the role of nonexperts in a technical controversy. CERB was asked to review the debate among scientists on the safety of rDNA research; but it was not asked nor was it equipped or prepared to undertake a risk assessment. After receiving testimony from experts, CERB members weighed the strengths of the arguments and on that basis made their decisions.

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[8] A detailed account of CERB's decisionmaking process is contained in Sheldon Krimsky, "A Citizen Court in the Recombinant DNA Controversy," *Bulletin of the Atomic Scientists*, vol. 34, No. 8, October 1978, pp. 37-43.

In contrast, the Cambridge Scientific Advisory Committee was comprised of experts and nonexperts with respect to the problems of highly toxic agents. Of the 16 members, 10 had advanced degrees in one or more of the relevant fields: physics, chemistry/biochemistry, chemical engineering, biology, and public health. SAC was presented with three tasks: 1) to undertake a risk assessment of ADL's use of chemical warfare agents, 2) to make a determination about acceptable risks, and 3) to advise the city council on a risk management plan.

Although the structures and goals of the two social risk assessment processes differed, both SAC and CERB were given the charge of determining whether the respective research activities should be prohibited, unconditionally permitted, or conditionally permitted. Also, both processes resulted in a proposed framework of risk management involving the creation of a new institutional structure for the city.

Parties Affected by the Proposed or Actual Regulations

The first Cambridge rDNA law had a direct impact on biomedical scientists, including biochemists and molecular geneticists who study gene structure and function. The revised law primarily affected R&D firms that were investigating commercial and medical applications for genetically modified organisms. In the former case, scientists responded as a community to the prospect of being regulated and opposed differential standards of research between Cambridge and other parts of the country. In the latter case, Harvard and MIT joined with Biogen to ascertain the impacts of licensure on rDNA research in their respective institutions. The revised law created new formal requirements for academic and commercial institutions but the actual requirements for individual investigators in academe remained unchanged.

The Cambridge emergency order on nerve and blister agents did not single out the names of any institutions. However, no institution other than ADL is known to have been directly affected. The agents prohibited for use were taken directly from an ADL-DOD contract. For all practical purposes, therefore, the order was directed at ADL. The regulations covering the use of supertoxins recommended by SAC were, however, much broader in scope and, if passed, probably would affect research at other institutions. For example, SAC proposed that certain designated hazardous materials proposed for testing, use, storage, or disposal within the city must be reported to the Commissioner of Health and Hospitals at least 3 months prior to the date of planned entry into the city. The substances designated for reporting include: chemical warfare agents (as provided in a list), other nerve agents of different chemical structure to those listed when used in chemical weapons R&D, biological warfare agents, and other highly toxic agents as the Commissioner may designate. SAC also proposed that each use of the regulated agents be reviewed by the Commissioner and given a site evaluation in writing after appropriate information is provided. Should the Commissioner find that the use of the regulated chemical presented an unacceptable hazard to public health or safety, then a site assignment could not be given and the commissioner could prohibit the use of the materials. And, finally, SAC recommended that in addition to chemical warfare agents, the City of Cambridge develop policies to regulate other supertoxins.

To date, the city has not acted on these recommendations, which, if adopted, could significantly affect university research. At the least, the proposed regulations would apply to any experimental uses of substances designated by DOD as chemical warfare agents. Most broadly interpreted, the rules might regulate research employing any highly toxic chemical such as dioxins, chemotherapy agents, or potent mutagens. In the former case, the impact to academic scientists would be minimal for chemical warfare agents are not widely used in university laboratories (although analogs and close derivatives of them may be more readily found). In the latter case, many chemical and biomedical facilities would be affected because it is not uncommon to find some quantities of highly toxic agents in most well-equipped laboratories.

Legal Issues

The authority of cities and towns to enact health and safety regulations is firmly established under State laws. Both the rDNA law and the order on chemical warfare agents are examples of such powers exercised by the city of Cambridge. Three generic legal questions arise when the city regulates an activity under public health and safety statutes: 1) Are there any procedural errors in the process of issuing regulations? 2) Is the regulatory action arbitrary or capricious? 3) Is the regulation preempted by or does it conflict with Federal and/or State laws or authority?

No legal challenges were directed to either of the Cambridge rDNA laws. Similarly, laws of other cities and towns were also enacted and implemented without challenge.[9] Because no Federal rDNA laws were passed and because Congress has yet to express a policy on whether it occupies the field of regulations for gene-splicing, the issue of preemption in either of the rDNA cases is generally considered weak. NIH guidelines may have the force of law to those who receive Federal funds, but the agency lacks legislative authority to preempt other political jurisdictions from passing more stringent rules.

Harvard and MIT were prepared to challenge the legality of the rDNA laws if they had prohibited or substantially inhibited scientific research. As it turned out, the universities avoided litigation and accepted rDNA standards somewhat stricter than those which were required of other academic institutions in the country. The "Balkanization" of standards for scientific research was a great concern to researchers during the Cambridge debate and for years thereafter as Congress considered Federal legislation; but the predicted adverse consequences on scientific research from local rDNA laws never materialized. None of the 13 communities that passed rDNA legislation have placed undue burdens on scientific research, and scientists have adapted easily to the additional local requirements.

Cambridge's public health regulation on chemical warfare agents took a different legal course. ADL challenged the order immediately after it was issued. Counsel for ADL argued that the regulation was invalid on all three grounds cited above. The legal question with the widest implications was whether DOD-sponsored research performed at a private facility was protected against local regulations. Is this a case where Federal supremacy over local authority applies?

ADL offered the following arguments:

1. Congress authorized DOD to establish a chemical warfare program and this includes the authority to issue requirements for handling and disposing of chemical warfare agents.
2. The framers of the U.S. Constitution as well as Congress intended the Federal Government to have exclusive responsibility for national defense. The city's regulation prohibiting ADL from conducting defense-related testing of chemical warfare agents is tantamount to interference with government functions and represents a clear conflict with the Federal interest.
3. If Cambridge is free to prohibit such work by a duly contracted agent of the Federal Government, then so too is any other community. If all jurisdictions followed Cambridge, Federal programs in chemical warfare research would be frustrated.
4. Because ADL is a contractor of the government, the firm is invested with "derivative sovereign immunity," which allows the supremacy clause of the Constitution to apply to it with equal force to that of the Federal Government.

Counsel for the city argued that two conditions must be satisfied for Federal supremacy to hold. Either the Federal Government has explicitly preempted the field of toxic substances regulation or a fundamental conflict exists between the Federal and local governments on the regulation of these substances. According to the city, Congress never stipulated that testing of toxic substances would be exclusively regulated by the Federal Government. Moreover, on the question of jurisdictional conflict, the city maintained that the Federal Government possesses other facilities at which to carry out such tests. The facts do not demonstrate that prohibition of such tests in Cambridge represents a fundamental conflict between local and Federal purpose.

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[9] Sheldon Krimsky, "Local Monitoring of Biotechnology: The Second Wave of rDNA Laws," *Recombinant DNA Technical Bulletin*, vol. 5, No. 2, June 1982, pp. 79-85. To date, the following cities and towns have passed ordinances on recombinant DNA research. In Massachusetts: Amherst; Belmont; Boston; Cambridge; Canton; Lexington; Newton; Shrewsbury; Somerville; Waltham. In other States: Berkeley, CA; Princeton, NJ; Emeryville, CA.

On December 14, 1984, a State Superior Court judge ruled that Federal supremacy was not in effect for this case. Subsequently, on February 26, 1985 after reviewing arguments on the reasonableness of the regulation and its legality with respect to State law, the same court found the regulation "valid and enforceable." The city's arguments prevailed on all the legal points.

The Massachusetts Supreme Judicial Court also upheld the regulation, stating in its decision on August 1, 1985, that the regulation constituted a permissable attempt by the city to protect its inhabitants under local police powers derived from State statutes. The court rejected arguments by ADL that the ruling violated the firm's right to due process or constituted an unjustified interference in its contract with DOD. The court also ruled that the regulation is not invalid under the Supremacy Clause of the U.S. Constitution. The SJC failed to find within Federal statutes congressional intent to preempt local communities from passing health and safety regulations for chemical warfare agents. The court affirmed the right of local health authorities to prohibit activities as long as the regulations are not "unreasonable, arbitrary, whimsical, or capricious."

The context of legal similitude for the rDNA and the chemical weapons issues is very narrow. In both cases there are Federal guidelines or regulations for certain experimental activities. In both cases, the city chose to augment or supersede the role of a Federal agency. But from that point, the legal issues evolved quite differently.

IMPACTS OF THE CITY'S INTERVENTIONS BEYOND ITS BORDERS

The 1976 rDNA debate was covered extensively by the national and international media. Little research has been done on the impact of the debate outside the United States, but within this country there is documentation about direct and indirect effects on other municipalities and on national policies. Nearly two dozen city/town governments and State legislatures considered passing laws that would have extended coverage of the NIH guidelines to privately funded institutions. In response to the first Cambridge debate, two States and four local governments enacted rDNA legislation. Several communities modeled their citizen review process closely on that of Cambridge. The City of Berkeley passed an rDNA law that incorporated verbatim sections of the Cambridge ordinance. By 1978, however, the ripple effect of the first Cambridge rDNA controversy had taken its course and was affecting only a handful of university communities. The national debate subsided and so did the involvement of town and municipal bodies.

A second wave of community responses broke after Cambridge passed its 1981 law. An additional seven communities in the greater Boston area, including the City of Boston, passed similar laws directed at commercial biotechnology but also applicable to scientific research. In an unusual case, a law passed in the City of Waltham, Massachusetts, prohibited the use of human experimental subjects in recombinant DNA research. This is, perhaps, the first U.S. law prohibiting human genetic engineering.

The rDNA events in Cambridge also had reverberations in Congress. The publicity surrounding the Cambridge controversy was one of the key factors influencing some Members of Congress to file bills that would place gene-splicing under Federal regulation. Of the two leading bills, the Senate version, sponsored by Edward Kennedy (D-MA), paid close attention to the events in Cambridge.[10] The Kennedy bill contained weak preemption language, signifying a respect for the rights of communities like Cambridge to establish standards of safety for rDNA research in excess of those required by the Federal Government. Despite considerable congressional activity, however, no legislation emerged during the years of peak public interest between 1977 and 1980.

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[10] The leading congressional bills were introduced by Representative Paul Rogers (D-FL), H.R. 4759, on Mar. 9, 1977, and Senator Edward Kennedy (D-MA), S. 1217, on Apr. 1, 1977.

The extensive publicity around the citizen participation process in the Cambridge rDNA affair probably did have some influence in the reorganization of the Recombinant DNA Advisory Committee (RAC) in 1978. Department of Health, Education, and Welfare (HEW) Secretary Joseph Califano expanded the size of the RAC from 16 to 25 members to accommodate more public participation. Cambridge became a model for environmental groups like Friends of the Earth and the Sierra Club which lobbied Congress and HEW for broadening public involvement in the decision-making process. One of the members of the Cambridge citizens' committee was appointed to an expanded RAC in 1979 when 30 percent of its membership was drawn from the fields of public health and public interest.

The ADL debate over the testing of chemical warfare agents is over a year old. It has been accompanied by a limited amount of national publicity. Lower court decisions were picked up by three national television news networks. The ABC TV news magazine program "20/20" produced a segment on the debate. National Public Radio also broadcast a program on "Morning Edition," October 3, 1984, describing the Cambridge-ADL debate.

Cambridge is one of at least 12 cities in the United States containing firms that have contracted with DOD to conduct research with chemical warfare agents. This list became public as a consequence of the "20/20" broadcast. There have been no reported actions taken by any of these communities in response to the Cambridge prohibition, but it is too early in the legal process to speculate whether the case might serve as a precedent for local regulation of research involving highly toxic chemicals.

ARGUMENTS FOR AND AGAINST REGULATIONS

Recombinant DNA Controversy

For Regulation

NIH released its first set of guidelines for rDNA research on the same day the city of Cambridge held public hearings to discuss Harvard's planned P-3 laboratory. The guidelines were issued in response to concerns by molecular biologists that gene splicing might result in the unexpected creation of a new epidemic pathogen, toxin-producing bacteria, or a coliform bacteria harboring a human cancer virus. In Cambridge, the debate centered on whether the research should be done at all and whether the NIH guidelines provided a sufficient margin of safety against an accident or unintended outcome.

Scientists spoke forcefully on both sides of the issue. Those against the use of a P-3 facility at Harvard for rDNA experiments cited three deficiencies in NIH's role as the overseer of the research. First, they argued that the guidelines were constructed from untested *a priori* hypotheses and they placed little confidence in the regulation's effectiveness as a containment strategy. Second, it was pointed out that the NIH guidelines had no force over R&D activities that were not funded by the Department of Health and Human Services. At the time, biotechnology firms had not sought entry into the city, but that was thought not to be far off. Third, opponents argued that NIH had not enlisted sufficient participation from the general public and other segments of the scientific community. Some scientists maintained that rDNA molecule technology was an unknown and uncharted area of research with unpredictable risks. They felt it should not be done in proximity to classrooms and other research activities.

When the city was approached by the first of several biotechnology firms planning to locate in Cambridge, a new set of public anxieties arose. By that time the city's rDNA law had been in effect for 3 years. The principal rationale for passage of the revised law was the concern over large volumes (over 10 liters of culture) of genetically modified organisms, and the potential hazards associated with occupational exposure and environmental release.

The citizens' committee was not aware of any regulatory body at the Federal or State level which set standards for large-scale work involving rDNA molecules. After consultation with experts in fermentation engineering and the sterilization of spent organisms in large vessels, the citizens' committee proposed revisions in the 1977 law. Among the restrictions cited in the revised law was:

> There shall be no deliberate release into the environment, that is the sewers, drains, or the air, of any organism containing recombinant DNA and further that any accidental release shall be reported to the Commissioner of Health and Hospitals within five days.[11]

The new law created a system of accountability according to which biotechnology firms were required to have special licenses for large scale work. The system included periodic inspections to ensure that the environmental release provision was respected by the technology and practiced by the institution.

Against Regulation

The principal opposition to local regulation of rDNA research in 1976 came from scientists, graduate students, and university administrators. They emphasized the confidence that the vast majority of scientists had in the NIH guidelines. RAC was cited as an exemplary system of oversight and one that a local community could not duplicate. The importance of uniform national guidelines was stressed. Science, it was said, cannot flourish in a patchwork of regulations. If Cambridge enacts restrictive rDNA regulations, scientists will find it necessary to move away from the city to other areas more conducive to their research. The universality of the scientific method requires uniformity in the social context within which research is carried out. This norm would be violated if each community passed its own research guidelines.

Opponents of regulation also stressed the benefits of rDNA research. These benefits might be delayed significantly if restrictive local regulations were established. Those critical of local regulation emphasized that the risks of rDNA research were at best hypothetical and quite likely nonexistent, while the benefits were real. Not a single case of illness was linked to an agent of an rDNA experiment. In their view, a significant margin of safety was already provided by the NIH guidelines.

The Case of Chemical Weapons Research

For Regulation

The arguments for regulating chemical warfare agents centered around the potential adverse public health consequences associated with their accidental or intentional release. The Cambridge Scientific Advisory Committee examined several worst-case scenarios in which quantities of 10, 100, and 500 ml. of nerve agent were hypothetically released from the testing facility. SAC concluded that such an accident was unlikely but not impossible; in the event of a 100 ml. release, members of the general public might be located within range of lethal doses of such agents.[12] The committee cited an independent consultant report that estimated between 10 to 30 members of the general public might be located within range of lethal levels of such agents in one of several worst-case scenarios. The case in question involved a sudden release of 100 ml. of sarin in the form of a gaseous cloud.[13]

The SAC report stated that there were no satisfactory regulatory mechanisms for managing the use of supertoxic agents in the city. Having concluded that even relatively small quantities of chemical warfare agents used in R&D could pose a risk to the public, the committee proposed a municipal ordinance for regulating such agents in particular and supertoxins in general. SAC made no distinctions in its regulatory program between R&D or between university and nonuniversity uses of supertoxins.

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[11] Krimsky, et al., *Municipal and State Recombinant DNA Laws*, op. cit.

[12] Scientific Advisory Committee for the City of Cambridge, op. cit., p. 2.

[13] TRC Environmental Consultants, Inc., *Community Risks from Experiments with Chemical Warfare Agents at Arthur D. Little* (Hartford, CT: 1984).

More than half the members of the committee favored a ban on any research involving chemical warfare agents on the grounds that the "risks associated with any such work [are] unacceptable." A smaller number of members expressed opposition to the research on ethical grounds—that any work on chemical weapons is morally reprehensible. They believed that no clear distinction can be drawn between offensive and defensive research. The city's legal arguments for its regulation, however, focused exclusively on issues of public health and safety. City council debates also centered on public health issues in contrast to the rDNA episode when some councillors questioned the morality of genetic engineering. To some degree, the psychological impact of the term "chemical warfare agents" was a relevant factor, however, in the public's sensibility to the issue.

Against Regulation

Arthur D. Little's case against the city's ban can be classified according to the following categories: 1) safety of the facilities; 2) errors and deficiencies of the SAC report; 3) discriminatory nature of the action; 4) misunderstood goals of the research; 5) compliance by ADL to all Federal, State, and local laws and regulations; and 6) violation of Federal supremacy.

1. The company maintained that its laboratory is among the safest that exists for the work intended. The laboratory satisfied DOD specifications for handling chemical warfare agents. ADL was also in compliance with Federal and State environmental regulations. The firm argued that its laboratory advances the state of the art for the safe handling of hazardous substances. To further increase the margin of safety, ADL agreed not to store more than certain minimum volumes of the chemical agents.

2. ADL also argued that the committee's technical analysis was flawed. According to company spokespersons, the report drew conclusions from assumptions that do not reflect ADL's operations. One of the risk scenarios developed by SAC assumed greater quantities of chemicals than ADL claimed it would ever have on hand. Furthermore, SAC did not determine the probability of its worst-case accidents. It did not describe how chemicals stored in secure containers could be released into the environment from some accident. The SAC report did not take account of the many barriers there are to the kind of accident it postulated. In fact, if there were an accident, the company held, the effects would not be felt beyond ADL. According to the company, the city's attempt to ban the five chemicals was unreasonable and invalid because it was not shown that the research posed any potential health hazard.

3. The company also believed that the city's action was discriminatory. Selected city officials, including the city manager, were first informed about ADL's plans for the laboratory in January 1983, but it was more than a year later, and after an occupancy permit was issued, that ADL was ordered to cease its testing. In its letter to the public, ADL wrote: "We worked closely with the Cambridge City Manager and the relevant public safety officials throughout the planning and construction of the facility, and they expressed complete confidence in its safety and security. We hired outside consultants to check our findings and designs."

ADL also faulted the city for not allowing the company to remedy any defects that may have been found in its safety program. As a result, the city's prohibition imposed upon ADL nearly a million-dollar loss in the cost of the laboratory in addition to substantial losses in present and future DOD contracts.

ADL also argued that it had been selected out for regulation. According to the company, there are many risks to the people of the city that are far greater than its testing program, yet the city focused attention on a state-of-the-art testing laboratory that uses small quantities of chemicals. If the city wishes to regulate toxic substances, ADL proposed, it should treat all institutions and all substances on a comparable basis. The determination to regulate should not depend on whether the research is done at a profit or nonprofit institution, involves basic or applied science, or is carried out under contract from DOD or under a grant from NIH.

4. ADL correctly surmised that some of the public concern over its research was motivated

by concerns over the morality of chemical weapons research. In a letter to the public, ADL clarified the ethical basis of its contract with DOD:

> We believe something must be done to control the threat of uncontrolled toxic chemicals in the environment. We have the professional capabilities and the resources to help solve some of the inherent problems. That is why we went to the expense of constructing a safe, secure, facility for research designed to find better ways of protecting people from the effects of uncontrolled environmental hazards."

The firm assured the citizenry that its research on chemical and nerve agents is exclusively for "defensive and protective purposes."

> We are using existing substances in analytic tests in order to develop better methods of detecting minute quantities of these agents in the environment and safer, more effective means of destroying them on a large scale. We are also working to develop better protection, including clothing for people who might be exposed to these substances.[14]

5. All Federal, State, and local regulations had been met before ADL's lab went into operation. The facility had been inspected by DOD, State agencies, and city officials. The company received an occupancy permit. The city's ban thus was perceived by the company as an afterthought to all regulations that were in effect prior to and during the time the laboratory was under construction.

6. The supremacy arguments have been outlined in detail in the section of this report comparing the rDNA research and chemical weapons testing. In summary, ADL contended that the city has no authority to interfere with a contract of the Federal Government when all Federal and State safety standards are met. The city's ban on the testing and storage of the agents is argued to conflict with the Federal authority governing national defense and is therefore unconstitutional. If other municipalities passed similar prohibitions, there would be a direct conflict between the policies of the U.S. Government and the actions of local communities. Under such conditions, the policies of the Federal Government are preemptory, the company stated.

Although the principal opposition to the city's action banning the testing and storing of five chemical warfare agents came from ADL, there was some criticism expressed by university representatives about the proposed regulations for supertoxins contained in the SAC report. MIT officials argued that SAC's approach to chemical regulation would have a "harsh and adverse effect on the conduct of research in chemistry, biology, nutrition and food science" at universities. Because SAC made no provisions for volume exclusions in its proposed regulations of chemical warfare agents or closely related chemicals, many substances used in the course of research would fall under the proposed criteria. According to the MIT officials, if enacted, these criteria would be an obstacle to scientific research without offering any additional protection to public health.

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[14] John F. Magee, President of Arthur D. Little, Letter to the Public, Jan. 28, 1985.

GENERAL POLICY IMPLICATIONS

The central issue underlying both case studies is the extent to which local communities are justified in regulating research. Beyond this similarity, there is considerable variation in how these cases relate to issues of scientific freedom and social accountability. The rDNA case involves a well-defined scientific population, a Federal funding agency, local universities, and a city government. The case of chemical weapons testing is about private contract research. It too involves city government, and a Federal funding agency. But a well-defined scientific constituency is absent.

Three policy issues stand out in the rDNA episode. First, should science be self-regulated and therefore insulated from State and local laws? Second, does NIH oversight of rDNA experiments provide a legal basis for Federal supremacy and, if not, should Congress establish legislation toward that purpose? Third, to what extent, if at all, is scientific research a right granted under the First Amendment?

NIH has been the de facto regulator of federally funded rDNA experiments. Scientists, however, have had an influential role in the establishment and implementation of guidelines. Through the NIH structure, the molecular geneticists have had what has been ostensibly a self-governing apparatus somewhat analogous to a peer review process. The Cambridge debate threatened this tradition of self-governance which began at Asilomar and evolved into the formation of the Recombinant DNA Advisory Committee. The city also challenged the idea of uniform safety standards for experiments in molecular genetics.

Although Cambridge scientists were the only ones directly affected by the city's intervention, the possibility of multiple sets of guidelines for rDNA technology, based in part on local standards, troubled scientists throughout the country. Many biologists who opposed congressional intervention, preferred it over a patchwork of regulations. According to Rockefeller University biologist Norton Zinder, the uniformity of scientific practice transcends local interests:

> The proliferation of local options with different guidelines in different states and different cities can only lead to a situation of chaos, confusion, and ultimately to hypocrisy amongst the scientists involved.[15]

Most legal scholars agreed that the NIH guidelines did not provide a basis for preempting the Cambridge law. No judicial challenge was made on the reasonableness of the Cambridge rDNA law in the context of the Federal guidelines. Perhaps because the Cambridge rDNA laws (first and second) added very little to the substance of the NIH guidelines, a legal challenge was avoided. Had the city banned rDNA research, the question of preemption most certainly would have been addressed in litigation, if not through congressional action.

Preemption was not the only legal question raised in the early rDNA debate. Facing the prospect of Federal regulation, some scientists argued that rDNA legislation would infringe on their rights to engage in research. Prompted by several inquiries, in 1977 the American Civil Liberties Union (ACLU) began a task of formulating a policy on whether, or to what extent, scientific inquiry is a civil liberty protected under the first amendment. Special committees of the ACLU began drafting policy statements that provided a civil liberties perspective on scientific research. Thus far, the Board of Directors of ACLU has not reached a consensus on the wording of such a policy.

ADL's legal battle with Cambridge did not attract sympathetic support from other scientists. Most university-affiliated scientists did not view the possible restriction on specific contract research as a conflict between the local community and freedom of scientific inquiry. The applied nature of the testing work and the fact that the results would probably be classified contributed to this attitude.

The policy dilemma is best interpreted as a conflict between the rights of a firm to accept Federal contract research under Federal guidelines and the rights of a city to set its own standards of public health and safety including a prohibition of research it deems hazardous. The outcome of the ADL case has implications for any federally contracted research on nongovernmental property that involves hazardous or potentially hazardous procedures or materials. For example, a community might decide to establish prohibitions against certain animal experiments. As a consequence, contract research and basic science would be affected adversely. Cases of this nature have not been widespread; but they are appearing. In Washington Grove, Maryland, residents have expressed opposition to the testing of chemical nerve agents in the vicinity of a school. Morris Township, New Jersey, has been the site of a controversy involving Bell Communications Research (Bellcore), an AT&T spin-off company. At issue has been the use and storage of highly toxic gases, such as arsine, commonly used in semiconductor research (see discussion in app. C). Neither congressional policies nor case law has settled the debate over Federal supremacy in these cases. If the ADL litigation continues beyond the Massachusetts courts, Federal judicial interpretation may set some explicit parameters for local control of private sector research.

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[15] National Academy of Sciences, *Research With Recombinant DNA: Academy Forum* (Washington, DC: December 1977).

Chapter 8

Research Policy Issues That May Warrant Congressional Attention in the Future

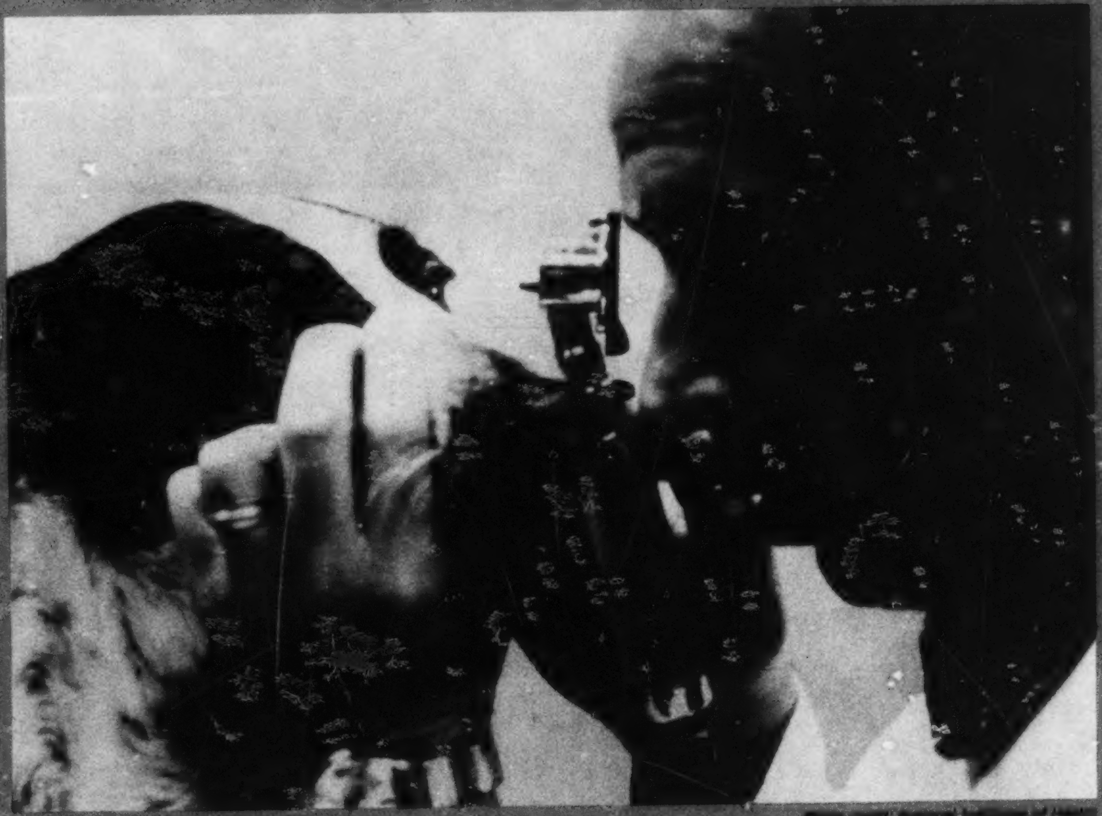

Photo credit: National Institutes of Health

Chapter 8

Research Policy Issues That May Warrant Congressional Attention in the Future

In OTA's brief survey of laboratory directors d research administrators,* the respondents ere asked to reflect on how things have changed om when they were just starting out in science d to list the major constraints then as opposed now. The trend most noted by both groups is nderstandably the increase in administrative and ureaucratic" requirements of grant procurement d administration. Fifty percent of the univer- y administrators and 32 percent of the lab di- ctors noted that administrative requirements for e investigator have increased substantially. me spent on detailed administrative work means ss time and money spent on research.

Other changes in the regulatory environment ted by the respondents were the greater chance litigation and the appearance of more actors volved in the scope and definition of research. espondents see this latter trend as a result of in- eased Federal funding for research, which nec- sarily involves more political actors, and in- eased media coverage, which attracts more blic attention to the research process. Many so mentioned increased controls on dissemina- on of research results as being a significant difference between the climate of, say, 30 years ago and today.

About one-third of the respondents stated that they were not aware of any research areas where the trend is toward fewer rather than more controls. Of those laboratory directors who did cite an area where controls have eased, 16 percent felt that changes in the National Science Foundation (NSF) procurement and granting procedures have helped to ease the administrative controls resulting from grants arrangements with that agency. Recombinant DNA research was also listed as an area where the trend has been toward more relaxed regulations. Other areas mentioned were human subjects research (where expedited review processes and exemptions have made the approval process less difficult) and a tendency toward decreased controls at the Federal level with simultaneous increase in controls at the State, local, and institutional levels.

If these research policy issues which have dominated the discussions for the last decade appear to be either resolving or, at least, not creating major controversies among the research community, then what issues *do* appear to be emerging for congressional attention?

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*For details, see box in ch. 6.

VHO BEARS THE BURDEN OF PROOF?

The burden of proof for control of research ap- ears to be changing. Increasingly, the individ- l researcher or research facility must prove that e research is safe rather than the regulator prove at it is unsafe.

A shift in responsibility is clearly occurring in e case of restrictions on scientific and technical mmunication. Under schemes proposed in 1980 the American Council on Education, for example, cryptology researchers were asked to carry the burden of deciding which papers to submit to the National Security Agency for review.[1] A similar shift in the burden of responsibility occurred in 1980 changes in NSF grant policy, which made the grantee responsible for notifying

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[1] Massachusetts Institute of Technology, *Interim Report of the Committee on the Changing Nature of Information* (Cambridge, MA: Mar. 9, 1983), Section 4.5.

NSF if, in the course of an NSF supported project, "information or materials are developed which may affect the defense and security of the United States."[2]

If a fundamental constitutional right is involved, then in the past the courts have placed the burden of proof on the government to show a compelling need to infringe. But some legal scholars argue that the situation is now muddied because it is increasingly difficult to distinguish between pure speech and "impure" special action.

[2] National Science Foundation, *Grant Policy Manual*, Section 794c.

THE SCIENTIST'S ROLE IN ASSURING SAFE RESEARCH

One of the principal unresolved issues is that of who should be involved in the regulatory process. What is an appropriate role for the individual scientist, for a professional science or engineering society, or for the public?

To what degree should the scientific community itself take central responsibility for both policing its own safety procedures and participating in the broadscale development of regulation? There are differing views on the extent to which scientists should be involved. Do scientists have some special right to be exempted from consideration of these issues? Or is it as John Edsall wrote in 1975:[3]

> The responsibilities are primary; scientists can claim no special rights, other than those possessed by every citizen, except those necessary to fulfill the responsibilities that arise from the possession of special knowledge and of the insight arising from that knowledge.

The conflict between these varying interests is made clear in the specific provisions of the Export Administration Act, for example, where scientists, whether employed by academic institutions or industry, are expected to comply with the requirements of the Act and other "applicable provisions of law" when communicating research findings "by means of publication, teaching, conferences, and other forms of scholarly exchange."[4]

Many agencies have reached out to the affected research community, asking scientists to review proposed regulations, both formally and informally, and thereby hoping to assure that the regulations are written in such a way that they are enforceable and can and will be complied with (i.e., are not far-fetched). Such an approach tests those scientists' belief that the regulations are necessary to protect society. For example, some ". . . social scientists argue that in the case of recombinant DNA the process was flawed, precisely because the political authorities put too much reliance in the judgement of the researchers themselves" and that this situation led to "the capture of a regulatory agency by those it is supposed to regulate."[5] Others argue that the recombinant DNA case was "a model of responsible public policy decisionmaking for science and technology."[6]

How much should research be controlled by legal regulation, how much by institutional rules, and how much left to informal practice or to the codes or guidelines of professional societies? Strong arguments can be made that, when restraint is desirable, it should not involve the government. Regulatory enforcement, court cases, or congressional legislation may be inappropriate settings in which to make social decisions about the dangers and risks of research. Neither the current regulatory laws nor the agencies that enforce them are geared to address social or ethical issues. For many of the recent regulatory debates involving science, Congress has legislated solutions to fit one particular situation or crisis. While these procedures or rules may work well to adjudicate among differing scientific or legal aspects of problems, they are not always constructed in such a way as to resolve or negotiate compromise easily on moral or ethical points. Critics of a new line of research may be left to feel that they have no real forum from which to effect change.

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[3] John T. Edsall, *Scientific Freedom and Responsibility*, report of the American Association for the Advancement of Science, Committee on Scientific Freedom and Responsibility (Washington, DC: American Association for the Advancement of Science, 1975), p. 5.

[4] Harold C. Relyea, "The Export Administration Act of 1985: Implications for Scientific Communication," memorandum to the Committee on Scientific Freedom and Responsibility, American Association for the Advancement of Science, June 8, 1985, p. 9.

[5] Susan Hadden, as quoted in Sanford A. Lakoff, "Moral Responsibility and the Galilean Imperative," *Ethics*, vol. 191, October 1980, pp. 110-116.

[6] Harold P. Green, "The Boundaries of Scientific Freedom," *Regulation of Scientific Inquiry*, Keith M. Wulff (ed.) (Boulder, CO: Westview Press, 1979); reprinted from *Newsletter on Science, Technology, & Human Values*, June 1977, p. 118.

How extensive and complete should regulatory legislation be? If the decision is to rely on self-regulation, what criteria will be used? The philosophy behind both the Institutional Review Board (IRB) system and the Institutional Biosafety Committees is a form of "monitored self-regulation,"[7] in which the process of regulation is subject to review and monitoring by government authorities. The extensive use in the U.S. regulatory system of consensual voluntary codes and standards* is in this tradition, but this self-regulation for certain forms of research appears to have been questioned in many recent cases (e.g., animal experimentation). Should sanctions be imposed on professional communities or institutions that fail in their self-regulation? Or shall the disciplinary action continue to be directed at individuals?

One alternative to increased regulation might be better education of the young scientists in the rationale for and the ethical aspects of regulation. Today, such education occurs primarily through apprenticeship, through informal learning. Congress might be asked to consider encouraging—e.g., through fellowships—education in the ethics or procedures of regulation.

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[7] Harvey Brooks, Benjamin Peirce Professor of Technology and Public Policy, Harvard University, personal communication, 1985.

*See discussion in ch. 4.

EX POST FACTO RESTRICTIONS ON RESEARCH COMMUNICATION

An individual researcher and the Federal Government often can have overlapping but not identical interests in suppressing or disseminating scientific and technical information. In this respect, controls on research resemble government controls in all parts of society. "Most decisions about regulation involve decisions among competing societal 'goods,' not decisions between 'goods' and 'bads'."[8] To achieve greater benefits, society may be inclined to accept greater risks; but in some situations the risks are experienced differentially by particular groups or individuals. The Department of Commerce has, for example, interpreted such normal scientific activities as presenting papers and talking with colleagues as a potential "export" of technology, which could be construed as requiring a scientist to obtain an export license before participating in such activities. In the opinion of some observers, this interpretation constitutes a prior restraint on speech, a "governmental intrusion on the scholarly exchange of ideas."[9]

These interests have been placed in especially sharp contrast when the Government has attempted to restrict communication about research undertaken independently and without Federal support, or when the Government classifies retrospectively research that was not conducted under classification or even with military funding. Similar issues are raised when there are attempts to control the dissemination of militarily or internationally "sensitive" but previously unclassified information or to control access to facilities.[10] In the decision to classify or control scientific information, the risks to national security must be weighed against the long-term value of free flow of information among a nation's scientists and against principles of scientific and academic freedom.

One consequence of U.S. restrictions may be the inhibition of U.S. scientists' access to information abroad. Several European members of the

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[8] Ibid.

[9] American Civil Liberties Union, *Free Trade in Ideas: A Constitutional Imperative* (Washington, DC: May 1984), p. 18.

[10] Harold C. Relyea, *National Security Controls and Scientific Information* (updated 09/11/84), issue brief IB 82083, Library of Congress, Congressional Research Service, Government Division, Washington, DC, 1984.

North Atlantic Treaty Organization (NATO) are reported to be considering the establishment of a new technology transfer agency to coordinate their political response to the controls placed by the United States on the flow of advanced technology.[11] The NATO Science Committee recently wrote that, around the world, "certain important research institutions are . . . already being overcautious" in communication of research results.[12]

The Committee expressed fear that the combination of an increasing amount of classification—for reasons relating both to national military *and* economic security—and increased international industrial competition could impede cooperation between the scientific communities of friendly nations. They also emphasized that restrictions will make it more difficult for small nations to obtain access to much-needed research results and that more classification may lead to more costly duplication.

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[11] NATO Science Committee, "Open Communication in Science," *NATO Science & Society*, 1983.

[12] Ibid.

"GRAY AREAS" OF SENSITIVE INFORMATION AND BROADER CLASSIFICATION

"Significant attempts have been made to restrict the flow of information in cases where it has been felt that, though unclassified, it was of such sensitive nature that our 'enemies' could use it to their advantage."[13] For example, Executive Order 12356, a classification order issued by President Reagan, "appears to allow classification to be imposed at any stage of a research project and to be maintained for as long as government officials deem prudent."[14] John Shattuck, of Harvard University, observes that that order "could inhibit academic researchers from making long-term intellectual investments in nonclassified projects with features that make them likely subjects for classification at a later date."[15]

As discussed in chapters 3 and 4, the use of Export Administration Regulations and International Traffic in Arms Regulations to identify and control "gray areas" of research previously unclassified and usually not considered covered by those regulations has raised a number of questions about the potential of long-term adverse effects on the U.S. scientific base. Increasing the areas of unclassified but severely restricted information not only inhibits communication among colleagues who could benefit from interaction but may also point out to opponents those scientific areas of potential fast progress.

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[13] Alan McGowan, Scientists' Institute for Public Information, New York, NY, personal communication, 1985.

[14] John W. Shattuck, *Federal Restrictions on the Free Flow of Academic Information and Ideas* (Cambridge, MA: Harvard University, January 1985).

[15] Ibid.

IMPACT OF NEW COMMUNICATION TECHNOLOGIES

The information revolution creates new opportunities or methods for delaying or classifying information as well as opportunities for more open dissemination. "As long as there were significant delays in publication of new scientific results, the review process for commercially sponsored research offered only modest impediments to scientific openness."[16]

If recognized by the scientific community as a legitimate publication that signifies a claim to priority, publication on electronic networks could provide a new channel for scientific interaction. It could also have the effect of increasing the amount of classification of scientific information if, because of the speed of publication on such networks, the Government feels compelled to act quickly to classify without adequate information to justify such classification.

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[16] Brooks, op. cit.

New technologies also give rise to questions about how much control an originator/creator has over the research project's results or data, its intellectual property. This issue is discussed in OTA's forthcoming report on intellectual property.

PATENTS

Many observers propose the need for revision of the patent system because they believe that the existing policy inhibits the progress of science and stifles invention and innovation. Federal Government policy has been to retain title and rights to inventions resulting from federally funded research and development (R&D) made either by government contractors or grantees or by in-house government employees.[17] However, only about 5 percent of the 25,000 to 26,000 patents currently held by the government have been used.

A related issue is whether there is a need for a uniform government-wide patent policy. Several pharmaceutical firms have also begun to use the patent law to restrict research uses of patented products and procedures, even for experimental use (heretofore regarded as exempt).[18] Such action raises new questions about the interpretation of current law when there is competition in a fast-moving field and where the language of the law may be at variance with contemporary research practices.

An Organisation for Economic Co-Operation and Development (OECD) task force has recently recommended that OECD countries adopt the U.S. policy of making the date of conception, rather than the date of filing, the legal date of a patent. If this were followed, then pressure to keep data confidential pending patent filing would be much reduced because there would be a grace period of 12 months after publication for filing of a patent application. The main reason for delay of publication in most university-industry agreements is to allow time for filing for foreign patents. Revisions in the patent laws could therefore result in significant long-term effects on research.

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[17] William C. Boesman, "Government Patent Policy: The Ownership of Inventions Resulting From Federally-Funded R&D," issue brief IB78057, Library of Congress, Congressional Research Service, Science Policy Research Division, 1985.

[18] Jeffrey L. Fox, "Patents Encroaching on Research Freedom," *Science*, vol. 224, June 3, 1984, p. 1080.

PUBLIC EDUCATION ON THE BASIS AND PROCEDURE FOR REGULATION

Understanding of and education in science play a vital role in the public's willingness to support the regulation of research. If the public understands the inadvertent and unintended effects of government regulations, then it may be more likely to support changes in policy which more accurately implement the intent of the law. Many observers have described to OTA a growing disassociation between what the public believes should be controlled and what the government actions are controlling. The government is presumed to be acting on behalf of the public, but, for example, is there evidence of public support for the increased controls being placed on scientific communication?

As the case studies presented in chapter 7 and appendix C show, how the public perceives or calculates the risks of research may greatly influence its willingness to control research and may similarly influence public beliefs about *when* controls or legal regulation should be imposed.

SHIFT IN THE JURISDICTION FOR REGULATION

The discussions of such actions as the right-to-know legislation, the Arthur D. Little and Bellcore cases (chapter 7 and appendix C), and the animal experimentation controversy show that the public—through either community protest or referendum—can act to control, direct, or influence the topic choice, experimental procedures, or communication of science. Although the evidence is limited, such cases hint at the beginning of a jurisdictional shift in the regulatory arena for science, especially from the Federal to the State and local. This change may be a reaction to either real or perceived laxity in Federal regulations for health and safety protection, it may relate to broader issues of the exertion of local control over land use and community activity, or, in some cases, it does relate to the larger agenda of national political groups—e.g., protests linked to nationwide efforts to stop all nuclear power, abortions, or the use of animals in research.

This jurisdictional shift raises the spectre of a number of negative effects on research caused by inconsistencies or variations in the strictness of Federal and local regulations. As Allen G. Marr, Dean of the Graduate Division of the University of California, argued in a letter to OTA:

> Regulations promulgated uniformly on the basis of federal law are far superior to patchwork regulation by state law or local ordinance. Codes of ethical professional practice are an important complement but not a full substitute.

An issue raised by participants in the Arthur D. Little case (see ch. 7), was that protests over research involving hazardous chemicals might have the unintended result of segregating such research. States without the resources for developing comprehensive regulations (or for assuring compliance) might become dumping grounds for research no other States want.

Is there a need for a new jurisdictional framework by which Congress can deal with these issues, or are they best resolved at State and local levels?

GENERAL ISSUES

Underlying many of these issues are questions not resolvable through legislative activity but to which the Science Policy Task Force of the House Committee on Science and Technology, in its deliberations, should attend. Once societal constraints may be imposed, a fundamental question is that of what constitutes "research." For example, does there exist some constitutional protection for research, and if so what does the legal definition of "research" include? Does it include not only thinking about a problem or talking to other scientists but also experimentation? The definition of what is or is not *basic* research currently plays a role in the dissemination of Department of Defense (DOD)-sponsored research results. Defining a project as falling within Federal budgetary category 6.1 (fundamental research), for example, can determine whether or how it is classified by DOD.[19] The definition of what is or is not research also plays a role in regulation of biomedicine. Experimental surgical procedures, for example, may be justified as therapeutic and not be subjected to review by an ethics committee. A medical researcher who refers to a project as a "pilot study" or as "innovation" can keep it outside such regulatory control mechanisms as IRBs.[20] Better understanding of these and other definitional questions will be essential to future attempts to resolve many of the issues mentioned above.

In setting an agenda for science, should policymakers look only to the potential benefits of the research proposed or should equal consideration be given, before funding, to the risk posed by the research? If so, what parameters should be used to make those determinations? André Hellegers once said that he, for example, would "assign a very low priority" to any inquiry that "does not, *in the inquiry,* harm nature, but which may be dangerous in its consequence. . .".[21] Ruth Macklin made a similar point in her essay "On the Ethics of *Not* Doing Scientific Research" when she wrote:

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[19] Janice R. Long, "Scientific Freedom: Focus of National Security Controls Shifting," *Chemical & Engineering News*, July 1, 1985, pp. 7-11.

[20] Arthur Caplan, The Hastings Center, Hastings-on-Hudson, NY, personal communication, 1985.

> There is surely some disutility attached to an outcome that fails to benefit people who might otherwise have been helped by research. But unless we subscribe to a research imperative that places freedom of scientific inquiry above all other values when potential danger lurks, we need to examine closely the value dimensions of each instance of decisionmaking under certainty.[22]

To approach full understanding of this question, one must also consider what consequences—e.g., only the most probable or only the most negative—are to be included in such a determination and also what relative weights should be assigned to various potential outcomes. Is there not just one but a spectrum of possible ways in which society might use the results, and what relative weights can be assigned to the better or worse consequences?[23]

In setting funding priorities, Congress may increasingly have to confront determinations of what are the boundaries of control of science's overall agenda. Such questions have been raised in connection with the current shift toward military dominance of basic research funding and with the increased numbers of arrangements between universities and industry. Will such shifts result in increased, long-term restrictions on communication, and in controls on procedures as well as on agenda-setting? How might such changes affect—positively and negatively—the research process and the openness of scientific communication?

And, finally, as the case studies and many of the examples show, the flow of public information plays a significant role in the regulatory environment for science. There is, of course, an urgent need for truly sensitive information to be protected by the classification system, whether for reasons of military security or economic protectionism, and such arguments are equally valid for industrial or academic protection of intellectual property. Arbitrary and capricious use of secrecy and classification, however, may inadvertently damage the progress of science by inhibiting the free flow of information among researchers and the flow of information to the public. In the latter case, inadequate or incomplete information could, in fact, increase the probability of arbitrary regulation at the local level and, on matters relating to national policy debates, inhibit free political discourse.

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[21] André Hellegers, *Regulation of Scientific Inquiry,* Keith M. Wulff (ed.) (Boulder, CO: Westview Press, 1979).

[22] Ruth Macklin, "On the Ethics of *Not* Doing Scientific Research," *Hastings Center Report,* vol. 7, December 1977, pp. 11-15.

[23] Brooks, op. cit.

Appendixes

Appendix A

The Regulatory Environment for Science

Regulatory Forces on Specific Fields—Two Case Studies

These case studies illustrate the regulatory forces at work on two different research areas—agricultural research and research on acquired immunodeficiency syndrome (AIDS). The first area, agricultural research, is highly organized and highly controlled. Regional needs largely determine the substance and agenda of research, even though the actors who set the agenda may be part of centralized government or in a multinational corporation. Recently, two well-publicized legal actions have had a dramatic influence on the research process in agriculture, attempting to prohibit research from progressing on certain topics or in a certain manner. The second area, research on AIDS, offers an interesting contrast in the types of forces regulating a "hot" research field. Here, the methodological traditions of science and some significant liability and privacy issues may be colliding with the push by advocacy groups for acceleration of the research.

Regulatory Forces on Agricultural Research[1]

In April 1863, the U.S. Department of Agriculture (USDA) was given authority to use about 40 acres of land at the west end of the Capitol Mall in Washington, DC, as an experimental farm. Since then, food and agricultural research in the United States has expanded and now includes three major performers: the USDA; the State agricultural experimental stations (SAES), and private industry, all of which do both mission-oriented research and basic research.

For its research activities, USDA maintains three separate operating agencies—Agricultural Research, Cooperative Research, and Extension Service—and an Office of Science and Education, which sets broad agricultural research policies. The Agricultural Research Agency is responsible for most of USDA's in-house agricultural research and is accountable and responsive to Congress and the executive branch for broad regional, national, and international concerns. The Cooperative Research Agency administers Federal funds that go to States for agricultural research. The Extension Service disseminates research results through, for example, publications, public meetings, and demonstrations. The four SAES geographical regions are each headed by a deputy administrator and typically include a central station located often on the campus of a State's land-grant university, and a number of branch stations throughout the State. Major private performers in agricultural research include such companies as General Foods Corp., Ralston Purina Co., and Campbell Soup Co..

In general, public sector agricultural research focuses on biological technologies, while the private sector sponsors research on mechanical and chemical technologies. In 1978, total Federal expenditures for all research and development (R&D) were $26.2 billion. USDA's expenditures were $381 million, or only 1.5 percent of the total U.S. R&D budget. The total private sector agricultural R&D budget is about three-fourths of the total USDA contribution.

A multiplicity of actors—consumers, producers, investors, in-house scientists, scientific societies, the regulatory agencies, the executive branch and Congress—thus determine research priority setting in agricultural research. Within the SAES system, for example, line item administrators and scientists set specific project priorities according to their assumptions about what is the greatest need in their field and what would be of greatest value to the State. Traditionally, federally sponsored research has been managed through a classification system based on geography, type of research (i.e., basic or applied), the problem area, and program structure. A less direct, but no less influential determinant of research direction has been Federal environmental and safety regulations, such as regulations on chemical residues or additives in food.

Recently, two separate legal actions have introduced controversy into what has usually been a quiet region of the scientific community. In 1979, attorneys filed a lawsuit, on behalf of 17 farm workers and the California Agrarian Action Project, which charged the University of California with unlawfully spending public funds on mechanization research that displaced farm workers. That suit is still in litigation.

Mechanization research includes the development of machinery, crop varieties, chemical herbicides, growth regulators, and laborsaving methods of handling, transporting, and processing crops. Lawyers for the farm workers allege that such research displaces farm workers, eliminates small farms, harms consumers, impairs the quality of rural life, and impedes collective bargaining, thereby failing to satisfy the government's obligation to consider the needs of small and family farmers, as specified in various Land-Grant

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[1] This section summarizes material in U.S. Congress, Office of Technology Assessment, *United States Food and Agricultural Research System* (Washington, DC: U.S. Goverment Printing Office, December 1981).

Acts and the Hatch Act of 1877, which authorizes Agricultural Experiment Stations.

The plaintiffs are demanding that all mechanization research at the University of California be halted until a fund is created to be used to assist and retrain farm workers.[2] Their supporters feel that Federal funding for research on laborsaving devices is an improper use of Federal money; it is best supported by the marketplace because agribusiness is the primary group that stands to gain most from the benefits of such research. Opponents see it as a battle between consumerism and good science at best, and the imposition of Federal controls on research and a violation of academic freedom at worst. They cite many cases where mechanization research has resulted in lower prices for the consumer and more humane working conditions for the farm worker. The case, as yet unresolved, raises issues about: 1) the social costs of innovation through agricultural research, and 2) the legal and social responsibilities of those who conduct research that might adversely affect certain populations. In the legal sense, the case raises questions about the propriety of Federal expenditures for research activities that might primarily benefit private interests.

The other legal action and public protest, launched by activist Jeremy Rifkin and the Council on Economic Trends, has attempted to halt the deliberate release of genetically engineered products into the environment, a technology of potential use to the agricultural industry as a means of increasing and improving crop production. A Federal appeals court has ruled that experiments involving the release of genetically altered organisms into the environment can proceed, provided that their potential ecological effects have been properly evaluated. Rifkin's group has also filed suit along with the Humane Societies of the United States and the Minor Breeds Conservancy against the Department of Agriculture on the issue of transferring genes between species, such as injecting genes for human growth hormone into livestock to promote more rapid and exaggerated growth. As of September 1985, a hearing date had not been scheduled.

These actions demonstrate that even the most highly controlled of research fields may be disrupted by new regulatory forces.

Research on AIDS[3]

Much of what we know about the biology of acquired immunodeficiency syndrome (AIDS) is also a result of federally sponsored research activities; for example, Public Health Service (PHS) grantees "discovered" AIDS as a syndrome, PHS has conducted surveillance of AIDS, and PHS investigators and others have made significant scientific advances, including the discovery of the probable etiologic agent for AIDS. Furthermore, PHS investigators are extensively involved in collaborations with non-Federal researchers, both nationally and internationally. Thus, the environment in which AIDS research is funded, conducted, and reported is influenced not only by the politics of the disease (i.e., the special populations which it effects), but also by the traditional funding mechanisms, the grants review process, and the way in which commercial interest turns basic research results into vaccines. In the case of AIDS, these forces appear to have both contributed to and impeded the research.

Although AIDS funding increased substantially in fiscal years 1984 and 1985, the history of specific funding for AIDS has been marked by tension among the individual PHS agencies, Department of Health and Human Services (DHHS), and Congress. Through the Assistant Secretary for Health, individual PHS agencies have consistently asked DHHS to request specific sums from Congress; DHHS has submitted requests for amounts smaller than those suggested by the agencies; and Congress typically has appropriated amounts greater than those requested by the Department. Except when prodded by Congress, DHHS has maintained that PHS agencies should be able to conduct AIDS research without extra funds. However, threatened cuts in overall funding and personnel levels have restricted the ability of affected agencies to redirect resources.

An additional indirect influence on the research has been the uncertainty of project staff levels. At critical times in the planning stages, the number of personnel needed to conduct and support the research has actually been reduced in several of the PHS agencies. As a result, the PHS agencies have been unable to plan their activities adequately because they have not known how much funding and staff will be available to them. Now that an etiologic agent for AIDS has been discovered and the research could move into areas where several agencies have overlapping expertise, the jurisdictional uncertainty—because of the uncertainty in resource allocation—has intensified competition.

The question of whether AIDS funds should come out of existing PHS agency budgets, or whether such funds should augment agency budgets, also reflects concern about the perceived appropriateness of PHS funding of AIDS-related research and the perceived magnitude and importance of the AIDS epidemic. Some scientists have expressed concern that research on other diseases will suffer because funds are being transferred *from* these areas *to* AIDS-related research; other observers believe that AIDS-related research may be delayed because of wrangling over such transfers.

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[2] *California Agrarian Action Project (CAAP) et al.* v. *The Regents of the University of California,* Case 516427-5, Superior Court of the State of California, Oakland (filed Sept. 4, 1979).

[3] This section summarizes material in U.S. Congress, Office of Technology Assessment, *Review of the Public Health Service's Response to AIDS* (Washington, DC: U.S. Government Printing Office, February 1985).

In AIDS research, some sharing of information has taken place through the informal networks that exist among PHS agencies and among their researchers, but tensions also surround formal communication. Since the National Cancer Institute's work on HTLV-III was announced in April 1984, formal information-sharing on a management level has increased substantially, and centralized coordination of activities is also on the increase. Members of the PHS Epidemiology and Prevention Task Force have agreed to distribute articles prior to publication, and to discuss studies at the planning stage in order to avoid unnecessary redundancies and to ensure that all the necessary areas are being covered. Many of these sharing and coordinating activities would have taken place regardless of any directive from PHS central management, but in other instances, earlier PHS guidance might have led to better coordination—e.g., PHS might have directed the National Cancer Institute (NCI) to share AIDS virus culture with the Centers for Disease Control, an action which was not taken.

Another factor that may have impeded the generation and dissemination of information is the Federal grants application and approval process for extramural research. National Institutes of Health (NIH) research grants take about 16 months from conceptualization to awards; contracts, about 14 months. The first round of extramural grants awarded by NIH for AIDS research took 14 months to be processed, in part because of negotiations with the Office of Management and Budget over the specific language used in the agreements. Since that time, some steps have been taken to speed up the process, such as mail ballotting instead of face-to-face meetings by reviewers. Shortening the process, however, may only increase concerns about the quality of the research activities funded.

Federal regulations covering commercial development of drugs, biologics, and devices have also impeded open communication. In the United States, Federal policy tends to leave commercial development of technologies, including technologies derived from Federal biomedical research, to the private sector. Once under commercial sponsorship, R&D activities are considered proprietary and will not be made public unless voluntarily released. The Food and Drug Administration (FDA), therefore, cannot even divulge the protocols being used by the five companies under license from NCI to develop AIDS screening tests to Federal researchers who are not directly involved in these activities. Yet the Federal researchers will generally share their research, including their research materials; their primary concerns are the qualifications of the private researchers and the quality control processes they have established. In the case of AIDS, the sharing of information developed by commercial firms was enhanced in small part because PHS selected the companies that would get the HTLV-III culture developed by the NCI laboratory. Other laboratories, however, have now cultured the virus and sold or given it to companies other than those selected by PHS, and the status of those companies' activities is formally unknown to any Federal researcher at FDA.

Finally, AIDS has been described as a "legal emergency" as well as a medical crisis. Much of the concern centers on social discrimination experienced by members of the groups at risk to contract the disease, especially homosexual men and intravenous drug users. Two sections of the Public Health Service Act, therefore, have been used to protect confidentiality in federally sponsored research. Section 242a authorizes the Secretary of DHHS to protect the privacy of individuals participating in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, by: 1) withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals; and 2) prohibiting persons authorized to protect the privacy of such individuals from being compelled to identify them in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Section 242m(d) provides that information may not be used for any purpose other than the purpose for which it was supplied unless consent has been given.

As more is known about the relationship between HTLV-III and AIDS, or as other diagnostic tests are developed, confidentiality safeguards will have to be implemented without sacrificing the surveillance needs of public health officials or data sharing among researchers. Informed consent will be an especially difficult issue, for example, because the first test to be applied will detect exposure to HTLV-III only through the presence or absence of antibodies and persons who test positive may actually be carriers of HTLV-III, may develop AIDS, or may remain well. Regulatory decisions, therefore, will have to balance the public health concerns surrounding the transmissibility of AIDS with the social stigma or employment discrimination that may accompany identification as a potential carrier or potential victim.

Appendix B

Public Attitudes Toward Science*

The attitudinal environment for science includes the attitudes of the public toward science and technology in general or institutional terms. These attitudes may be usefully grouped as hopes and expectations, reservations and concerns, and confidence in the leadership of the scientific community. This appendix will examine both the literature and the data relevant to each of these three sets of attitudes.[1]

Hopes and Expectations

In broad strokes, the literature and the publication data from the 4 decades since 1945 portray a public that has a high regard for the past achievements of science and technology and high hopes for even more spectacular results in the future. Even though most Americans still see science as a magic black box,[2] the evidence is clear that they also believe that their current standard of living is in large part the result of modern science and technology. The substantial gains in medical science, for example, symbolize the achievements of science for most Americans.

The first national study of public attitudes toward science in the post-war years was conducted in 1957 by the Survey Research Center of the University of Michigan. Sponsored by the National Association of Science Writers (NASW) and the Rockefeller Foundation, the study was designed to assess the public's interest in and knowledge about science and technology, the major sources of information on current science issues, and the appetite of the public for science news. The study included personal interviews with a national probability sample of 1,919 adults and the field work was completed in early October 1957, just 2 weeks prior to the launching of Sputnik I. Inadvertently, the 1957 NASW study became the only existing set of measures of the attitudes of the American public toward science prior to the beginning of what is often termed the Space Age. The study offers, therefore, a unique opportunity to look back to the calm of the mid-1950s.

The 1957 NASW study found a public that believed that science and technology had won the war, created "miracle" drugs, and would continue to produce a cornucopia of benefits for American society.[3] Almost 90 percent of the American adults polled said that the world was "better off because of science." When asked why they thought so, slightly more than half cited medical advances and about 40 percent pointed to the American standard of living. When asked to name some potential "bad effects" of science, 90 percent of the adults in the study could not think of a single possible negative effect. Ninety-four percent of the population were willing to agree that science was making their lives "healthier, easier, and more comfortable." Ninety percent agreed that "most scientists want to work on things that will make life better for the average person" and 88 percent felt that science was "the main reason for our rapid progress." It would be hard to imagine a more supportive public.

Despite the influence of the space race and the continued growth of post-war science and technology, there were few efforts made in the 1960s to measure public attitudes toward science. The next systematic effort to assess the attitudes of the American people toward science and technology was initiated by the National Science Board (NSB) in 1972. As a part of its new Science Indicators series, the NSB decided to include a chapter on public attitudes toward science. The NSB staff prepared a set of questions and used the Opinion Research Corporation to collect national data sets in 1972, 1974, and 1976.

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*This appendix is based on an OTA contractor report written by Jon D. Miller, Northern Illinois University.

[1] The following data sources were utilized in secondary analyses. The 1957 National Association of Science Writers study was based on personal in-home interviews with a national probability sample of 1,919 Americans. The interviews were conducted by the Survey Research Center at the University of Michigan. The field work for this survey was completed just prior (about 2 weeks) to the launch of Sputnik I by the Soviet Union and is the last measurement of American attitudes toward science and technology prior to the Space Age. For a full description of the study and results, see R.C. Davis, *The Public Impact of Science in the Mass Media*, Survey Research Center monograph No. 25 (Ann Arbor, MI: University of Michigan, 1958).

The 1979 survey of public attitudes toward science and technology was based on personal in-home interviews of a national probability sample of 1,635 adults. Sponsored by the National Science Foundation (C-SRS78-16839), the field work was conducted by the Institute for Survey Research at Temple University. For a description of the design and results of the study, see Jon D. Miller, et al., *The Attitudes of the U.S. Public Toward Science and Technology* (Washington, DC: The National Science Foundation, 1980).

The 1981 survey of public attitudes toward science and technology was based on telephone interviews with a national probability sample of 3,195 adults. The study was sponsored by a grant from the National Science Foundation (NSF 8105662) and was conducted by the Public Opinion Laboratory at Northern Illinois University. For a description of the sample and results, see Jon D. Miller, *A National Survey of Public Attitudes Toward Science and Technology* (DeKalb, IL: Northern Illinois University, 1982).

The 1983 survey of public attitudes toward science and scientists was based on telephone interviews with a national probability sample of 1,630 adults. Sponsored by the Annenberg School of Communications at the University of Pennsylvania, the survey was conducted by the Public Opinion Laboratory at Northern Illinois University. For a description of the design and results of the study, see Jon D. Miller, *A National Survey of Adult Attitudes Toward Science and Technology in the United States* (Philadelphia, PA: University of Pennsylvania, Annenburg School of Communications, 1983).

The 1985 data on attentiveness to science policy were taken from a telephone survey of a national probability sample of 1,514 adults. The study was sponsored by *Family Circle* magazine and conducted by the Public Opinion Laboratory at Northern Illinois University. A technical report on this study will be released by the Public Opinion Laboratory in the fall of 1985.

The 1981-82 study of the attitudes of science policy leaders was based on telephone interviews with a national sample of 282 individuals. Sponsored by a grant from the National Science Foundation (NSF 8105662), the survey was conducted by the Public Opinion Laboratory at Northern Illinois University. For a description of the study design and the methods used to identify and sample science policy leaders, see Jon D. Miller and Kenneth Prewitt, "National Survey of the Non-Governmental Leadership of American Science and Technology," a report to the National Science Foundation, 1982.

[2] Jon D. Miller, "Scientific Literacy: A Conceptual and Empirical Review," *Daedalus*, vol. 112, No. 2, 1983, pp. 29-48.

[3] Davis, op. cit.

These NSB surveys found a public that still held science and technology in high regard, although less so than in 1957. In contrast to the almost 90 percent of the public that thought in 1957 that the world was "better off" because of science, only 70 percent of the public held the same view in 1972.[4] Similar results were obtained in the 1974 and 1976 studies.[5] While the absolute level was down somewhat, a substantial majority of the total public held very positive views of the contributions of science to American society.

In a 1979 national study of public attitudes toward science and technology, also sponsored by NSB, several of the 1957 questions were repeated, offering an opportunity for comparison across 2 decades. In 1979, 81 percent of the public still agreed that scientific discoveries were making their lives "healthier, easier, and more comfortable" and 86 percent expressed the view that scientific discoveries were "largely responsible" for the standard of living in the United States.[6] In a comparable national study in 1983, Miller found that 85 per cent of American adults continued to agree that science made their lives healthier, easier, and more comfortable.[7]

Although the material gains attributable to science have undoubtedly influenced public attitudes toward science, there is evidence that Americans also have a commitment to the value of science *per se*. In a 1983 national survey, Louis Harris found that 82 percent of American adults agreed that scientific research "which advanced the frontiers of knowledge" was worth supporting "even if it brings no immediate benefits."[8] Only 14 percent of Americans rejected this idea.

Evidence from the European Barometer indicates that western Europeans hold very similar views about the positive contributions of science and technology to their standard of living.[9] (See table B-1.) Approximately three-quarters of western Europeans were willing to agree with a statement that science had been and would continue to be a major factor in improving their lives. There was a high degree of consensus among countries, ranging from 80 percent in Northern Ireland to 65 percent in the Netherlands.

Table B-1.—European Attitudes Toward Science, 1978

Country	Percent agree
Northern Ireland	80%
United Kingdom	79
Italy	76
France	75
Ireland	75
West Germany	71
Luxembourg	70
Denmark	67
Belgium	66
Netherlands	65

"Science will continue in the future as it has done in the past to be one of the most important factors in improving our lives."

Another facet of the attitudinal environment for science is reflected by the public's expectations for future achievements. The belief that science has contributed to the health and comfort of the society is, of course, inherently retrospective; and so it is important to inquire whether the public expects similar achievement from science in the future, or whether the public thinks that the frontiers of science have been explored thoroughly. Beginning with the 1979 study for NSB, one series of questions have asked respondents to assess how likely it is that science will achieve certain results in the next 25 years. The results indicate that a large segment of the public holds high expectations for future outcomes from science and technology. By 1983, a majority of the public thought that it was "very likely" that within the next 25 years science would find a cure for the common forms of cancer, have people working in a space station, and find efficient sources of cheap energy (see table B-2).

In contrast, a substantial portion of the public indicated that they did not expect science to be able to cure mental retardation, communicate with alien beings, or put whole communities of people into outer space. These results indicate that the public does have some ability to differentiate between likely and less likely outcomes and that the optimism found in several previous responses is not a simple yea-saying reaction.

From these aggregate results, it would appear that a significant portion of the American people hold some positive general attitudes toward science. It is also important to inquire whether the attentive public[*] for

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[4] National Science Board, *Science Indicators—1972* (Washington, DC: 1973).

[5] National Science Board, *Science Indicators—1974* (Washington, DC: 1975); and National Science Board, *Science Indicators—1976* (Washington, DC: 1977).

[6] Miller, et al., op. cit.

[7] Miller, *A National Survey of Adult Attitudes Toward Science and Technology in the United States*, op. cit.

[8] Louis Harris, "The Road After 1984: The Impact of Technology on Society," a report prepared for the Southern New England Telephone Company, 1984.

[9] Jacques-Rene Rabier, *Euro-barometer 10a: Scientific Priorities in the European Community, October-November, 1978* (Ann Arbor, MI: Inter-University Consortium for Political and Social Research, 1981).

[*] In brief, the basic dimensions of an "attentive public" for science policy are high level of interest in the topic, combined with the perception of being adequately informed. For a discussion of this concept in more depth, see Jon D. Miller, "Public Attitudes Toward the Regulation of Research," contractor report prepared for the U.S. Congress, Office of Technology Assessment.

Table B-2.—Expectations for Future Scientific Achievements, 1979-83

Percent saying that the following results will be achieved in the next 25 years:	Year	Very likely	Possible, but not too likely	Not likely at all	Number of people surveyed
A cure for the common forms of cancer	1979	46	44	8	1,635
	1983	57	36	6	1,630
A cure for mental retardation	1983	11	40	47	1,630
A way to put communities of people in outer space	1979	17	38	42	1,635
People working in a space station	1983	52	34	12	1,630
Humans communicating with alien beings	1983	14	33	51	1,630
More efficient sources of cheap energy	1979	57	34	7	1,635
A safe method of disposing of nuclear wastes	1983	29	41	26	1,630

"Now let me ask you to think about the long-term future. I am going to read you a list of possible scientific results and ask you how likely you think it is that each of these will be achieved in the next 25 years or so."

science policy shares these same positive views of the past and future results of science. Fortunately, the national data sets collected in 1957, 1979, 1981, and 1983 are available for retabulation for this purpose.

The one question relevant to this section of the analysis that has been asked repeatedly throughout the last 3 decades has been the agree-disagree statement concerning the contribution of science to making our lives "healthier, easier, and more comfortable." A retabulation of three previous studies indicates that there has been some decline in the proportion of both the attentive public and other citizens willing to agree with the statement, but 9 of 10 members of the attentive public for science policy and 8 of 10 other Americans still hold that belief (see table B-3). At all three measurement points, at least 10 percent more of the attentive public were willing to agree with this view than were other citizens.

Some of the more recent data sets allow an examination of the difference in expectations between those who follow science policy matters and those who do not. In general, people who were attentive to science policy issues were more optimistic about the future achievements of science and technology than were those who were nonattentive (see table B-4). The general pattern of expectations by the attentive public and by the others did not differ significantly.

In summary, both the existing literature and selected retabulation of available data indicate that most Americans have a positive image of science and/or scientific research. Those who have a high level of interest in science and who feel reasonably well informed about it tend to hold even more positive views about the past and future benefits of science.

Reservations and Concerns

Throughout the post-war years, there has been some level of wariness about some of the possible negative effects of science among a substantial minority of the American people. On balance, these reservations have not offset the high levels of positive affect and expectation described above, but it is necessary to review and understand the magnitude and substance of these attitudes.

The 1957 NASW study found some reservations about the effects of science, but it was muted and most often accepted as the price of gaining good things from science. Slightly over 40 percent of the public were willing to agree that science "makes our way of life change too fast" and 23 percent agreed with the statement that "one of the bad effects of science is that it breaks down people's ideas of right and wrong." Although 70 percent of the adults in the 1957 study agreed that "the things that happen in this world are mostly controlled by God" and about half felt that "one of our big troubles is that we depend too much on science and not enough on faith," when asked to assess the net effect, 9 out of 10 concluded that the world was better off because of science. There was

Table B-3.—Attitude Toward Contribution of Science, by Attentiveness, 1957-83

	Year	Attentive public	Not attentive	Number surveyed	
				Attentive	Not attentive
Percent agreeing that science makes our lives healthier, easier, and more comfortable	1957	98%	93%	183	1,736
	1979	89	79	232	1,313
	1983	92	82	398	1,232

Table B-4.—Expectation for Future Achievements, by Attentiveness, 1979-83

Percent saying it is "very likely"that the following results will be achieved in the next 25 years:	Year	Attentive public	Not attentive
• A cure for the common forms of cancer	1979	55%	44
	1983	68	54
• A cure for mental retardation	1983	13	10
• A way to put communities of people in outer space	1979	13	10
• People working in a space station	1983	62	49
• Humans communicating with alien beings	1983	17	13
• More efficient sources of cheap energy	1979	76	53
• A safe method of disposing of nuclear wastes	1983	35	27
N (1979) =		307	1,328
N (1983) =		398	1,232

"Now let me ask you to think about the long-term future. I am going to read you a list of possible scientific results and ask you how likely you think it is that each of these will be achieved in the next 25 years or so."

some wariness, but not enough to offset the desire for increased health and comfort.

Karen Oppenheim repeated some of the 1957 NASW items in a national survey conducted by the National Opinion Research Center in 1964 and found that the level of public wariness or concern was increasing.[10] The NSB-sponsored studies in the early 1970s found the same trend.

Four of the items originally used in the 1957 NASW study were replicated in a 1983 survey sponsored by the Annenberg School of Communication at the University of Pennsylvania.[11] A comparison of the results indicates that the reservations expressed by those citizens included in the 1957 study have remained largely unchanged over the last quarter century.

The concern over the impact of science on the pace of change in society has also continued at virtually the same level. In both years, about 4 in 10 Americans expressed some concern that science was causing our lives to "change too fast" (see table B-5).

Table B-5.—Public Concerns About Science, 1957-83

	Year	
	1957	1983
• We depend too much on science and not enough on faith	50%	50%
• One trouble with science is that it makes our way of life change too fast	43	44
• The growth of science means that a few people could control our lives	32	35
• One of the bad effects of science is that it breaks down people's ideas of right and wrong	23	29
Number	1,919	1,630

Finally, these data indicated a persistent public concern about the potential for a few people to control the lives of the total society, using the power of science. In both years, about one-third of the adult population was willing to agree with the statement that the "growth of science" meant that a few people could "control our lives."

Recent studies indicate a renewed concern about the tie between science and weapons. A 1983 national survey by Harris found that 74 percent of adults in the United States were willing to agree with the statement that "with the development of nuclear, chemical, and biological weapons, science and technology may end up destroying the human race."[12] Another 1983 study found that one-quarter of the adult population thought that it was very likely that "wars in space" would occur in the next 25 years and an additional 36 percent of the American people thought that space wars were "possible."[13]

Do people who pay more attention to science (the "attentive public") have the same kinds of reservations as those reviewed above? A retabulation of the 1957 and 1983 data indicated that the attentive public holds many of the same reservations found in the previous data, but that the proportion of persons holding those reservations is slightly lower among the attentive public than other people (see table B-6). Although 4 in 10 members of the attentive public were concerned that society depends too much on science and not enough on faith, only 2 in 10 felt that science tended to break down people's ideas of right and wrong. The proportion of the attentive public concerned about changes in the pace of life and in the loss of the control of their lives to science did not differ significantly from the proportion for the nonattentive public.

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[10] Karen Oppenheim, "Acceptance and Distrust: Attitudes of American Adults Toward Science," master's thesis, University of Chicago, 1966.

[11] Miller, *A National Survey of Adult Attitudes Toward Science and Technology in the United States*, op. cit.

[12] Harris, op. cit.

[13] Miller, *A National Survey of Adult Attitudes Toward Science and Technology in the United States*, op. cit.

Table B-6.—Concerns About Science, by Attentiveness, 1957-83

	Year			
	Attentive		Not attentive	
Percent agreeing that	1957	1983	1957	1983
• We depend too much on science and not enought on faith	44%	43%	50%	53%
• One trouble with science is that it makes our way of life change too fast	34	36	44	48
• The growth of science means that a few people could control our lives ..	31	31	32	38
• One of the bad effects of science is that it breaks down people's ideas of right and wrong	16	24	24	32
Number	183	321	1,736	1,309

In summary, from the literature and from selective retabulation of previous data, it appears that a substantial portion of the American people hold some reservations about the impact of science on society. In the context of the very positive views found in the preceding section, it would appear that a significant portion of the American people recognize and understand that science involves both the potential for substantial benefits and the possibility of damage or misuse.

Confidence in Science

Given the combination of positive hopes and expectations and the simultaneous level of concern, how does the public reconcile these attitudes? Is there an overall view of science? In general terms, the attitude research data from the last three decades suggest that people have concluded that the benefits outweigh the potential harms from organized science in the United States.

As noted earlier, 88 percent of the adults studied in 1957 reported that they felt that the world was better off because of science.[14] The preceding analyses have demonstrated that the level of concern was as high in 1957 and in the early 1980s. The conclusion that the world was still better off for the contributions of science could be interpreted, therefore, as an assessment that the benefits outweighed the past and prospective risks.

Beginning in the 1970s, the surveys sponsored by the NSB asked each respondent to make an assessment of the relative benefits and harms and to weigh the two. Similar questions have been asked since that time by Cambridge Reports.[15]

The data from the last 15 years indicate that a solid majority of Americans believe that science does more good than harm (see table B-7). Only about 1 in 20 Americans believe that science does more harm than good, but about one-third of U.S. adults are unsure as to where the balance falls. Some of this uncertainty may reflect a lack of interest or information. About 5 percent of current respondents are simply unable to answer the question.

Although the exact items discussed above have not been used in a survey that would allow the separation of attentives and nonattentives for analysis purposes, the 1983 Annenberg study did include two items that reflect the same attitude. Each respondent was asked to agree or disagree with the statement that "the benefits of science outweigh whatever harm it does." Two-thirds of the attentive public agreed with the statement in comparison to 55 percent of nonattentives.[16] The same sentiment was measured with a paired statement worded in the other direction. When asked to agree or disagree with the statement that "science is likely to cause more problems than to find solutions," only 16 percent of the attentive public and 27 percent of the nonattentive public agreed. These results suggest that those who are interested in science issues and who follow science policy matters believe that the benefits of science outweigh its potential harm. This same view is reflected in the larger public, but it is not likely to be as solidly rooted in the larger population as it would be in the attentive public.

A second approach to reconciling the potential for good and harm from science is reflected in measures of confidence in the leadership of organized science. Most Americans have considerable pressure on their time and do not normally set aside a significant portion of time to consider the flow of issues in areas like science policy. If people (especially those attentive to science) have confidence in the leadership of major scientific organizations and corporations, then the leaders can be relied on to monitor the process and the public can wait until a real controversy emerges before becoming concerned about the issue.

The evidence from the General Social Survey [17] indicates that the leadership of the scientific community has been and continues to be held in high esteem (see table B-8). The only major institution in American society that has consistently claimed a high level of confidence from more Americans has been medicine, which may be viewed as at least closely related to the scientific community.

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[14] Ibid.

[15] National Science Board, *Science Indicators—1984* (Washington, DC: 1985).

[16] Miller, *A National Survey of Adult Attitudes Toward Science and Technology in the United States*, op. cit.

[17] J.A. Davis and T. Smith, *General Social Surveys 1972-1984: Cumulative Code Book* (Chicago, IL: National Opinion Research Center, 1984).

In summary, the literature and the reanalysis of previous data can be interpreted to indicate that most Americans see the benefits of science as greater than any potential harms or risks. This view is apparently held even more firmly by the attentive public for science policy. The evidence may also be interpreted to indicate that the leadership of the scientific community is held in high regard, implying a degree of trust in their monitoring of the work of organized science. But it should be noted that no major survey to date has specifically addressed the philosophical and political issue of direct regulation of scientific research. Episodes such as those discussed in chapter 7—and the existence of considerable congressional legislative activity resulting in regulation—can be interpreted just as strongly as indicators of, if not a lack of trust, at least a wariness on the part of some communities and constituencies.

Table B-7.—Public Assessment of the Risks and Benefits of Science, 1972-85

Science and technology ..... Year	do more good than harm	do more harm than good	do about the same amount of each	dont know/ not sure	Number
1972	54	4	31	11	2,209
1974	57	2	31	10	2,074
1976	52	4	37	7	2,108
1983	73	3	21	3	1,466
1984	63	5	27	5	1,864
1985	58	5	32	5	1,866

"Overall, would you say that science and technology do more good than harm, more harm than good, or about the same amount of each?"

SOURCES: Opinion Research Corp. (1972, 1974, 1976), Cambridge Reports (1983, 1984, 1985).

Table B-8.—Public Confidence in Science and Selected Other Institutions, 1973-84

Have a "great deal of confidence" in:	1973	1974	1975	1976	1978	1980	1982	1984
Medicine	54	60	50	56	46	52	46	52
Scientific community	37	45	38	43	36	41	38	47
Education	37	49	31	37	28	30	33	29
Organized religion	35	44	24	30	31	35	32	32
Military	32	40	35	39	29	28	31	37
Major companies	29	31	19	22	22	27	23	32
Press	23	26	24	28	20	22	18	17
Television	19	23	18	19	14	16	14	13
Organized labor	15	18	10	12	11	15	12	9
Executive branch	29	14	13	13	12	12	19	19
Congress	23	17	13	14	13	9	13	13
Supreme Court	31	33	31	35	28	25	30	35
N =	1,504	1,484	1,490	1,499	1,532	1,469	1,506	943

"I am going to name some institutions in this country. As far as the people running these insitutions are concerned, would you say you have a great deal of confidence, only some confidence, or hardly any confidence at all in them?"

SOURCE: James A. Davis and Tom W. Smith, *General Social Surveys Cumulative File, 1972-1984* (Ann Arbor: Inter-University Consortium for Political and Social Research, 1984), p. 152.

Appendix C

Environmental Concerns and Laboratory Siting: The Morris Township-Bellcore Case*

From February 1984 to May 1985, Morris Township, New Jersey, was embroiled in a controversy over the siting of a new research facility for Bell Communications Research, Inc. (Bellcore). The site plan of the proposed telecommunications research complex was debated extensively before the township planning board. At issue was the storage, use, and disposal of highly toxic and flammable gases. A group of residents formed the Concerned Citizens of Morris Township (CCMT)—an organization that spearheaded opposition to the research facility on the grounds that the work being planned there was potentially hazardous to public health and environmental quality. The Morris Township-Bellcore case draws attention to the efforts by citizens to set community standards of acceptable risk for privately financed research that requires the use of toxic materials. This brief case study summarizes the key events of the controversy, examines the legal basis of local regulation for the proposed research, reviews the justifications for and against siting the research facility, and finally, casts some preliminary comparisons to the two Cambridge, Massachusetts, cases discussed in chapter 7, in which recombinant DNA research and chemical warfare agents were regulated.

Historical Background

This case began like many land use decisions in communities throughout the United States. In the late 1970s, residents of a suburban neighborhood in Morris Township, New Jersey, raised concern over the development of a parcel of land adjacent to single-family subdivisions and a recreational area. The issues expressed during this period were predominantly those of traffic, noise, density, and aesthetics. In February 1980, after 15 public hearings over a 12-month period, the Morris Township planning board approved a plan submitted by the Southgate Corporation, developer of the site. The 58-acre parcel, called the Southgate Office Park Complex (Southgate Complex), was designated exclusively for office use.

Three years later, during the summer of 1983, with three office buildings under partial completion, the Southgate Corporation leased the site to Bell Communications Research, Inc. (Bellcore), a research organization owned by seven regional telephone companies. Bellcore is a by-product of AT&T's court-ordered divestiture of the Bell System. The Bell System Plan of Reorganization stipulated that the regional telephone companies create a central services organization to provide them with research and technical services.

On behalf of its tenant, the Southgate Corporation submitted an amended site plan on December 1983, which included the construction of an additional building devoted to research, and the use, as a laboratory, of two floors of a building previously approved as office space. Bellcore had planned to locate its Morris Research and Engineering Center at the Southgate location. A number of AT&T employees at Bell Labs facilities in Murray Hill, New Jersey, and Whippany, New Jersey, were expected to be transferred to the new center.

The proposed facility was devoted to advanced research in semi-conductors and fiber optics. This type of research commonly employs toxic gases such as arsine, phosphine, and diborane as well as liquified hydrogen.

Residential abutters to the site had attended a planning board meeting in February 1984 to discuss traffic patterns when they learned that toxic and flammable gases would be used under the amended site plan. Within a month, a core group of residents organized themselves into CCMT.

The citizens framed their opposition to the research facility on two principal grounds: 1) the health effects of an accidental release of toxic gases into their neighborhoods, and 2) a potential release of untreated or partially treated toxic effluent from the research facility into Loantaka Brook—a major tributary of the Great Swamp National Wildlife Refuge.

CCMT's main effort to prevent construction of the research facility was directed at the Morris Township Planning Board, a body consisting of nine appointed members legally responsible for land use decisions. Over two dozen public hearings were held by the planning board on the Bellcore case between December 1983 and May 1985. CCMT brought in paid consultants, some from outside the State, to testify in its behalf on the potential hazards to the community of the proposed facility. Eventually, CCMT drew support from a broad range of constituencies covering Morris Township and neighboring communities. Included among these were: Harding Township Environmental Commission; over 50 Harding residents; the Great Swamp Watershed Association; 14 civic associations with a putative representation of 2,000 households in Morris Township and neighboring communities; and an official of the U.S. Fish and Wildlife Service.

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*This case study was prepared for OTA by Sheldon Krimsky, Tufts University.

A letter signed by 14 representatives of civic associations expresses the intensity of public opposition:

> We question the need for Bellcore to impose the laboratory on a community that does not want it . . . . We emphatically state that the Bellcore laboratory is not welcome and that we will pursue every means available to expose and publicize the fact that, in this instance, Bellcore has failed to fulfill its role as a responsible corporate citizen . . . .[1]

What started out as a controversy involving abutters to an industrial site, soon evolved into a regional conflict over a proposed research and engineering center. As community pressure grew, so did Bellcore's impatience with the uncertainty of locating its new research home. The company made serious attempts to communicate its position that "the small quantities of chemicals that [the company] plans to use and the 'state-of-the-art' safety systems and procedures that it plans to employ will make the Southgate facility safe beyond any reasonable question whatsoever."[2]

In May 1984, Bellcore submitted an environmental information document to the planning board, describing its prospective laboratory operations, providing a representative chemical inventory for the new complex, and outlining safety procedures for the storage and handling of toxic materials. The company also hired risk assessment consultants to present its case before the planning board. Bellcore scientists provided an additional source of technical assistance to the company during the protracted debate.

In the 18-month period during which the planning board held public hearings on Bellcore's proposed research complex, proponents and opponents of the amended site plan were assigned scheduled sessions at which to present their respective arguments. On May 3, 1985, the planning board prepared for a final vote on the site plan. However, at the outset of the session prior to the vote, Bellcore made an unexpected announcement that it was withdrawing several controversial elements of its site plan including the new laboratory building, and the use of certain toxic and flammable gases. The planning board hastily accepted the modified proposal by a vote of 9-0. Realizing that even a vote in its favor would not end the controversy or the delay in construction, the company appears to have capitulated to the concerns of the citizen protestors. In response, the citizen's group chose not to appeal the final decision of the planning board—despite some uneasiness among CCMT members that they had not seen a completed version of the adopted site plan. This decision brought to a close an 18-month controversy over potentially hazardous research in telecommunications.

The Legal Dimension

Local planning boards derive their authority to exercise land use controls from State statutes. In New Jersey, Chapter 57 of the State Land Development Ordinance sets forth principles of municipal land use controls that include the promotion of public health and safety and protection against man-made and natural disasters. In the written opinion of the Morris Township counsel, "both municipal land use law as well as the Morris Township ordinances provide sufficient legal basis to deny the [Bellcore] application if the Board feels it would present an unacceptable risk." The key to the planning board's authority to proscribe research is in the interpretation of "unacceptable risk"—a vague and elusive term that was the centerpoint of much of the public debate.

The Southgate Complex is on land zoned for office and laboratory use, a point emphasized by Bellcore in its repeated contention that the amended site plan was in conformity with zoning requirements for the parcel. CCMT claimed that it was within the purview of the planning board to restrict research activities that pose a threat to human health, public safety, or environmental quality, even though the parcel is zoned for laboratory use. It argued that the zoning classification "research" is only a guide. Each activity must be carefully examined under this broad category (which includes everything from pencil and paper operations to the storage and use of hazardous chemicals) to determine whether it conforms to community standards of acceptable risk.

Acting in a quasi-legal manner but without strict rules of evidence, the planning board heard testimony from both sides, cross-examined witnesses, and permitted adversaries to question one another. A decision by the planning board is subject to an appeal in the State courts if the petitioner files the appeal in accordance with accepted guidelines.

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[1] Thomas Fuschetto, Jr., "Bellcore Protest Continues to Build," *Observer-Tribune*, Mar. 28, 1985.

[2] N. Michael Grove, Vice President and General Counsel, Bellcore, letter to James Stenger, Concerned Citizens of Morris Township, Mar. 11, 1985.

Citizen opposition to the facility was not directed at a particular research program per se, but rather at the chemical substances that were a critical part of the research activities.

Arguments For and Against a Research Ban

In its presentation before the planning board, Bellcore maintained that the site plan was in conformity to the zoning requirements of the parcel. Moreover, the proposed laboratory facility was designed to meet or exceed all Federal, State, and local laws on handling toxic materials. Company officials argued that "their plans are a logical extension of work done safely since 1941 at Bell Labs in Murray Hill where Bellcore scientists are working now until their company opens a home for them."[3]

Bellcore cited results of its commissioned risk assessment studies that examined the case of a worst-credible arsine leak. The conditions defining the worst-credible case are a failure in the mechanical scrubber (a device that filters out unwanted gases) resulting in a slow leak of arsine, or an accidental release of arsine as a result of a tube fracture. According to those studies, the maximum exposure of any citizen in the community would be about one fortieth of the safe arsine levels permissible for workers.

The risk assessment consultant to CCMT developed a worst-case scenario that differed considerably from cases cited by Bellcore. The storage of 1,500 gallons of liquid hydrogen on the roof of the laboratory building was the basis of one potential worst-case accident. A CCMT consultant cited as a plausible event a large hydrogen leak that could cause an explosion that would rupture the arsine tank and send toxic gases out toward the neighborhood.

CCMT was uncompromising on the matter of storing toxic gases on the roof of the proposed facility. The citizens group was not persuaded by company statistics on the low probability of hydrogen explosions, or the gas detection and monitoring systems planned for the new facility. Opponents of the facility fixed their attention on the worst-case explosive release of toxic gases. That became the standard against which they would judge acceptable risk.

An article in *Technology Review* which was distributed widely among members of CCMT fueled the citizens' resolve against accepting a compromise on the storage of toxic gases. Passages of the article read:[4]

> Acute inhalation [of arsine gas] can cause rapid destruction of red blood cells, followed by severe kidney damage, and if the patient is not immediately treated—death. Given sufficient low-level exposure over time, arsine also may be carcinogenic. The accidental release of the contents of a 20-pound cylinder of 100 percent phosphine would have to be spread over 1,792 acres—or 276 city blocks—before being diluted to the permissible exposure level of 0.3 ppm.

A second argument, which evolved somewhat later in the controversy, centered around the environmental protection of the Great Swamp National Wildlife Refuge. The proposed laboratory facility borders on Loantaka Brook, which flows into the Great Swamp. In response to the prospect of having pretreated emissions from the research facility flush into Loantaka Brook, a spokesperson for the Great Swamp Watershed Association said:

> [A]ny accidental discharge of hazardous materials from the Bellcore facility could impair the Woodland Treatment plant operation and seriously degrade water quality in the brook and further downstream in the Great Swamp.[5]

Environmentalists also expressed concerns about seepage of toxic materials into the groundwater from accidental spillage or a gas cylinder rupture. It was stressed that two streams running through Southgate feed a major drinking water source for 600,000 people. By dramatizing the potential environmental impacts, CCMT was able to build a broad coalition of supporters, consisting of civic associations and environmental protection groups, to oppose the Southgate site of the research facility.

A key difference between Bellcore and CCMT on the conceptualization of risk is exemplified by the terms "worst-credible case" and "worst-possible case" as applied to an accidental release of hazardous substances. In emphasizing the former phrase, Bellcore urged the community, in evaluating the risks, to consider plausible accidents and not extremely remote or unrealistic events. However, CCMT fixed on the worst event that was conceivable, without considerations of probability. Neither side introduced a quantitative assessment of the likelihood that any accident could take place. Each party argued its case within a preferred model of risk assessment, the choice of which is more a question of culture than of science. This difference made a negotiated settlement between adversary groups extremely difficult.

The Morris Township case is thus not one of a community regulating a form of objectionable research. Barely any interest was expressed by citizens about the nature of the semi-conductor and fiber optic research planned for the site. The entire focus of the debate was on the types of chemicals on site and the possibilities of their release into the environment. Had the planning board ruled against Bellcore, the decision would also not have established a legal precedent for similar cases that might arise elsewhere in the township. Planning board decisions are rendered for specific circumstances and do not accumulate as in case law. However, had such a decision been made, it is likely to have created for the township an informal regulatory precedent against similar proposals involving research with highly toxic gases. Although the company withdrew the proposal before a planning board vote was taken, a mood has been created in Morris Township that, while not codified into law, may be no less effective in proscribing such activities should they arise in a future site plan.

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[3] Timothy Mullaney, "Neighbors, Firm Struggle Over Chemical Risk," *Daily Record*, Apr. 22, 1985.

[4] Joseph La Dou, "The Not-So-Clean Business of Making Chips," *Technology Review*, May/June 1984, pp. 23-25, 32, 36.

[5] Sally Dudley, letter to the editor, *Observer-Tribune*, Mar. 21, 1985.

Comparisons With Two Cambridge, Massachusetts Cases

Table C-1 illustrates some comparisons and contrasts between the Morris Township case and the two Cambridge controversies. Notably, both the Arthur D. Little (ADL) and Bellcore cases involve private sector research for which highly toxic chemicals are required. Citizens of both communities cast their opposition to the respective research activities on public health grounds emphasizing worst-case scenarios. Opponents of the research in both cases were not persuaded by comparative risk analysis and arguments that they consider the probability of a worst-case accident. Environmental factors became important in the Morris Township debate, but were of little significance in the issue of chemical warfare research. However, the morality of research was discussed, to some degree, in both the debate over rDNA molecules and chemical warfare agents. Moral discourse about the nature of the research program did not arise among Morris Township citizens.

Bellcore's research program is a mixture of basic and applied science/engineering. The character of its research is a blend of what we would find at a university and what might be carried out at ADL. In Morris Township, the restraints on research came prior to the construction of a laboratory; that compares favorably with the rDNA case. In contrast, ADL had initiated its research before local restraints were imposed.

The social instruments for regulating research are markedly different between the Cambridge and Morris Township cases. The Cambridge city council and the health commissioner played key roles in the control of rDNA molecules and chemical nerve agents. In contrast, the township planning board acted as the exclusive social instrument for regulating Bellcore's research program. The public health officials of the township did not have a visible role in the controversy.

Whereas codification of research restrictions emerged in both the Cambridge cases, no formal restrictions on research were imposed in the Morris Township situation. In the latter case, withdrawal by Bellcore of its proposed solid state laboratory revealed the importance of a local cultural barrier to specific types of research. The barrier, although informal and uncodified, may have the persistence and efficacy of a law.

Table C-1.—Comparison of Three Cases Involving Local Control of Research

Category of comparison	rDNA—Cambridge	Arthur D. Little (ADL)—Cambridge	Bellcore—Morris Township
Type of research	Basic science	Applied chemical and engineering	Basic and applied science and engineering
Nature of institutions	Academic/nonprofit	Consultant/for profit	Private sector/for profit
Stage of the research at outset of local intervention	Not yet begun	7 months ongoing	Not yet begun
Source of research funding	NIH and NSF primarily	DOD	Private sector: regional telephone companies
Origins of controversy	National and within scientific community	Local and centered on a city and two towns	Local and centered on a township
Stimulus of local involvement	Newspaper story on Harvard's plan to build P-3 genetics lab	Newspaper story on ADL's new lab for testing chemical warfare agents	Planning board hearing on site plan for commercial development
Primary regulatory agent	City council	Public health commissioner	Township planning board
Time period of controversy	Stage 1: 7 months Stage 2: 5 months	20 months as of July 1985	18 months
Codification of ruling	Municipal ordinance regulating rDNA activities	Public health order banning uses of certain chemical warfare agents	None; withdrawal of planned research by firm
Institutional response to community reaction	Universities accept temporary moratorium	ADL rejects moratorium; litigates public health order	Followed process through planning board; finally withdrew proposal, no litigation
Actual interference with research	No appreciable delay	Not prevented or appreciably delayed to date	Research was delayed and finally prevented at site
Judicial action	No legal test of moratorium or rDNA ordinance	Litigation taken on research ban	No litigation
Nature of community involvement	Primarily from academic sector; no grass roots organizations	No organized opposition at the early stages; intense community organizing after release of SAC[a] report	Organized opposition at the outset; coalition-building with other townships and regional groups
Perceived community risk	Unspecified speculative scenario of creation and release of disease-carrying organisms	Explosive release of nerve agents exposing residents	Explosion of hydrogen tank and release of arsine gas; also release of toxic chemicals into fragile preservation area and groundwater

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[a] Scientific Advisory Committee.

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